

THE DRUG REVIEW PROCESS IN B.C. – OVERVIEW

The Ministry of Health Services has two main goals for the B.C. PharmaCare program:

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 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.

In Canada, drug coverage reviews take place in three stages. See [Drug Review Process in Canada and B.C.](#) for a diagram of these stages.

Stage 1 – Health Canada (federal government review)

Before a manufacturer 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 drug manufacturing.

>>> Learn more about the federal drug review process at the Health Canada [Drugs and Health Products](#) web page.

Stage 2 – Common Drug Review (national review)

If a manufacturer wants provincial drug plans to cover their drug, they send a 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 reviews each drug. They study the drug information and advise whether or not provincial plans should cover it.

>>> To learn more, visit the CADTH and the CDR website.

¹ Except for Québec which uses a different drug review process.

Stage 3 – PharmaCare Drug Review (B.C. review)

PharmaCare carries out its own review before making a decision. This 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 PharmaCare’s review: (1) gather information and input, (2) review by the Drug Benefit Council and (3) decision by the PharmaCare.

>>> To learn more, see our [B.C. Drug Review Process diagram](#).

(1) Gather information and input — This is a vital step 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 BC PharmaCare coverage policies and potential cost impact in BC,
- input from practicing BC clinicians and experts, including family physicians and specialists, and
- input from B.C. residents who may be affected by a coverage decision.

(2) Review by the Drug Benefit Council (DBC) — The DBC is an independent advisory committee. It has 12 members. It includes nine experts in critical appraisal of medical reports, medicine, ethics, pharmacy and health economics, and three members of the public. The DBC reviews all the information and input for each drug submission. 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 our [Drug Benefit Council](#) web page.

(3) PharmaCare makes its decision after the federal, national and DBC reviews are complete. In making its decision, PharmaCare considers:

- the DBC’s recommendation,
- PharmaCare policy and plans for this type of drug and any other Ministry programs, and
- whether PharmaCare has the resources 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 our [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 a drug will be used to treat,
- their caregivers, and
- B.C. patient advocacy groups that represent B.C. residents who have the illness or condition.

>>> To learn more, visit [Your Voice](#) - our [public input web page](#).