Making Decisions about Funding for Cancer Drugs:

A Deliberative Public Engagement

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1. Purpose of this booklet

This booklet is meant to provide background information on the topic of making decisions about funding medications to treat cancer in British Columbia (BC). It explains what priority setting is, the costs of cancer drugs and how we know they work.

The information in this booklet was collected from academic literature, the media, and in consultation with experts. The purpose of the booklet is to give you a good information base for other conversations about cancer drug funding in our public health system. The hope is that it will encourage ongoing discussion and reflection on this topic.

Many cancer drugs in Canada are covered under a provincial health insurance plan, but some are not. This public engagement event will focus on what factors and values you feel are important for health-care decision makers to consider when determining what cancer treatments should be covered under BC’s provincial health plan.

In this booklet and in other discussions, “medications,” “drugs,” “treatments,” and “therapies,” are often used interchangeably.

A glossary and list of resources can be found at the end of this booklet. Glossary terms appear in bold lettering.

2. What is a “deliberative public engagement”?

Access to promising new treatments is sometimes restricted in order to support sustainable health care in order to ensure that the benefits of the health-care system are fairly distributed. Health economists, health researchers, clinicians, industry, and health administrators have the responsibility to make these decisions on behalf of the public.

A deliberative public engagement shifts the focus of discussions about these concerns from telling people what drugs are available to them to recognizing that Canadians should have a voice in decisions about the health care they receive now and in the future. A deliberative public engagement acknowledges that all citizens have important things to say about health and health policy.

This booklet informs a deliberative public engagement event as well as a wider public dialogue on the topic of funding for cancer drugs. For this engagement event, people from BC’s general population have been selected to participate. Random selection was used to reflect the diversity of life experiences, perspectives, and priorities of the people of BC.
This booklet and speakers at the event will provide information to support your engagement with the topic of funding for cancer drugs.

A deliberative public engagement allows members of the general public to learn about a challenging issue, share their perspectives on it, and work together to make recommendations for policy. A diversity of perspectives on the topic is welcome and respected, and not everyone has to agree on a way forward. In fact, people's agreements and disagreements on the topic can be used to help experts and government officials make decisions that reflect what society values most. This can help build public confidence in the decisions made as a result of the public engagement process.

**Previous deliberative public engagement events**

Deliberative public engagement has been used before in Canada to address social challenges in health care, research, and the environment. British Columbians have helped develop policies for biobanks, genome sequencing for salmon, and electoral reform.

To our knowledge, this is the first deliberative engagement event on funding for cancer drugs in BC.

This event is sponsored by research grants from the Canadian Institutes of Health Research and the Michael Smith Foundation for Health Research. The research team is led by researchers at the University of British Columbia, the BC Cancer Agency, and the Canadian Centre for Applied Research in Cancer Control (ARCC). ARCC is funded by the Canadian Cancer Society.

**Discuss the issues at home**

Health care is of concern to all of us. As Canadians, we pay for the health system through taxes and use it for regular check-ups and when we get sick. Some also participate in research studies or clinical trials. Please read this booklet carefully. If you choose, you can discuss the ideas with your family and friends. In your discussions, consider what should matter when deciding which types of cancer drugs should be covered in our public health system.

During the engagement event, you will have the chance to discuss a variety of perspectives on health. You will be encouraged to express concerns regarding ethical and economic issues related to funding cancer drugs.
### 3. Why focus on cancer drugs?

Statistics tell us about 2 in 5 Canadians will develop some form of cancer in their lifetime, and about 1 in 4 Canadians will die of cancer. In 2011, there were 23,829 new cases of cancer diagnosed in BC; this total is projected to increase by more than 45% to 34,666 new cases in 2027. This increase is largely due to BC’s growing and ageing population, as cancer is a disease that arises most commonly later in life. More than half of the newly diagnosed cases will be prostate, breast, lung and colorectal cancers.

The price of drugs to treat cancer is also on the rise year after year. In 2010-2011 alone, the annual growth in BC’s cancer drug budget increased 15% over the previous year.

#### BC Oncology Drug Budget

(annual growth)

<table>
<thead>
<tr>
<th>Year</th>
<th>Budget Growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>28%</td>
</tr>
<tr>
<td>2003</td>
<td>10%</td>
</tr>
<tr>
<td>2004</td>
<td>9%</td>
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<tr>
<td>2005</td>
<td>19%</td>
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<td>2006</td>
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<td>2008</td>
<td>14%</td>
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<td>2009</td>
<td>14%</td>
</tr>
<tr>
<td>2010</td>
<td>16%</td>
</tr>
<tr>
<td>2011</td>
<td>15%</td>
</tr>
</tbody>
</table>

Source: BC Cancer Agency

BC—like the other provinces—spends the largest portion (30.3%) of its health-care budget on hospital stays. Physicians’ fees (14.6%) and prescription drugs (13.2%) will account for the next largest shares of the BC health budget. Although prescription drugs takes up a smaller portion of BC’s health budget, innovative and costly new cancer drugs use up the budget quickly.

In cancer care, **decision makers** need to set priorities about which cancer drugs can be funded and consider whether the high price tags for many new treatments are justified by the often small increase in **health benefit** they provide over less expensive drugs. A decision maker may...
be the head of a cancer agency or local hospital, or a group of senior health-care administrators. Decision makers must balance the needs of patients to treat different cancers—e.g., childhood leukemia, lymphoma or prostate cancer—and determine if health-care dollars are better spent elsewhere, like supporting cancer prevention programs or employing more radiation therapists and hospital workers. These decisions involve trade-offs when there are not enough resources to fund everything needed.

4. Canada’s public health system

In Canada, the provinces and territories are responsible for the delivery of health care. They receive transfer payments from the federal government to help pay for health care.

Provincial governments decide how much of their health-care budget will go to prescription drugs and how much goes to hospitals and other medical services, such as cancer screening programs or hospice care. They weigh the possible health improvements and harms of each drug or service. They also look at the costs of funding it or not funding it, what is important to the residents of their province, and whether the money is better spent on a different drug or service.

Decision makers need to determine which drugs are appropriate to support. Making these sorts of decisions means priorities must be set. Priorities are set when there is not enough money to fund all the programs, medications and services needed. Trade-offs in funding cancer drugs involves assessing the health improvements and financial costs of one medication against another to treat the same health condition (such as breast cancer).

Trade-offs may also occur between different groups of patients, such as patients with breast cancer and patients with rarer forms of cancer. If not all of the health conditions and patients can be helped because resources are limited, decision makers must determine where the limited resources are best placed.

The Ministry of Health and other appropriate decision makers determine how funds are allocated within a province’s health system as a whole. Provinces also decide how much of their overall budget to set aside for other publicly funded programs, like education and social services.
Provinces work within their own existing health systems and patient populations. They therefore will have slightly different local health and spending priorities, and thus different local trade-offs. Consequently, not all provinces will make the same funding decision for a drug or service.

Some prescription drugs and other medical services, such as prescription eye glasses and some reproductive services, are not covered by a provincial health plan. Patients pay for these expenses out of their own pockets. Almost 1 in 10 Canadians is unable to afford the prescription drugs he or she needs. Some expenses not covered by a medical plan are partially tax deductible. Private or supplemental health insurance is available in Canada and is sometimes supplied through employers. Supplemental plans may cover some or all of these additional costs.

DID YOU KNOW?

The Canada Health Act states that all Canadians have access to “medically necessary” services, regardless of their financial circumstances. However, what is medically necessary is interpreted differently across provinces. Also, what is “medically necessary” is not the same as universal health care, so not all medical needs are covered.

The Supreme Court of Canada has recognized that resources to pay for health care are limited, stating that the health-care system “does not have as its purpose the meeting of all medical needs” but rather provides a “partial health plan.” (See Auton v. British Columbia, 2004.)

Questions to reflect upon:

• When is it acceptable for a prescription drug plan to set limits on what drugs are covered?

• How might BC’s publicly funded drug plans balance the financial and health needs of those who need expensive drugs with those who don’t?
5. How do medications get covered by a health plan?

Before any drug is available to Canadians, it must go through an extensive review process. Special advisory committees are set up for this purpose. The role of the *advisory committee* is to give advice—in the form of recommendations—to decision makers. Decision makers then determine whether the drug provides more health benefit than another similar drug, whether the decision reflects the values of the community, and whether it fits in to the overall budget.

Advisory committees are made up of individuals with different expertise and perspectives. They often include patients who have experienced the health condition for which the drug is intended. Advisory committees assess the drug using several factors, such as the amount of health improvement to expect, how it affects patients, and how much it costs.

The chart on the next page shows Canada's drug review process. A drug must go through three stages of review and approval before it is funded. In Canada, cancer drugs are evaluated and funded separately from other drugs at the national and provincial levels.
Drug Approval Process in Canada

Stage 1: Authorize for sale – Health Canada review

- A pharmaceutical manufacturer seeking to sell a new drug in Canada submits an application to Health Canada for review.
- Health Canada assesses the scientific information on the drug’s safety, clinical effectiveness, and the quality of its manufacturing process. Clinical effectiveness is how well the drug works to prevent or control disease and improve health.
- Health Canada’s approval of a drug for sale in Canada does not necessarily mean that the provincial and territorial governments will fund it.

Stage 2: Recommend to fund or not – the pan-Canadian Oncology Drug Review for cancer drugs or the Common Drug Review for non-cancer drugs

- Next, these two agencies review the medical research evidence (i.e., usually clinical trials) and costs to determine if the drug works better than the usual treatment and if the cost is reasonable.
- These agencies can make one of three types of funding recommendations to the provinces: ‘Recommend,’ ‘Consider with conditions,’ or ‘Do not recommend.’

Stage 3: Decide to fund – Provincial and territorial Ministries of Health and cancer agencies

- Finally, provincial and territorial Ministries of Health use the recommendations to make their own decisions in combination with input from their own expert committees and based on other considerations like the effect on health services and overall budget. Provincial governments and cancer agencies are not obligated to take the advice of the previous review.

Once a drug receives approval for funding in a province, it will be included on the province’s public drug formulary. A public drug formulary is a list of prescription drugs—including cancer drugs—that are funded by a provincial drug program. Each province decides what drug programs to offer and what drugs are publicly funded. Private insurers also vary in their drug coverage. As a result, there are differences in the Canadian health-care system that lead to unequal access to drugs between provinces.

DID YOU KNOW?

A public drug formulary is a list of drugs and drug products that are covered by a province’s public health plan. Not all drugs approved for use by Health Canada are listed on a province’s public drug formulary. Patients or private health plans must pay for prescribed drugs not covered by a public drug formulary.
Questions to reflect upon:

• Should differences in funding of drugs between provinces be tolerated?

In BC, PharmaCare covers most prescription drugs listed on BC’s public drug formulary and the BC Cancer Agency specifically covers the approved cancer drugs available in BC. Patients or private health plans must pay for prescribed drugs approved for use by Health Canada but not covered by a public drug formulary.

Dealing with uncertainty

Advisory committees and decision makers don’t always have clear-cut evidence to work with. For example, the results from clinical trials might differ slightly, depending on the size of the trials and the health outcome being measured, or a drug might shrink a 3mm cancer tumour but its effectiveness for 2mm cancer tumours is ambiguous. *Uncertainty* around the evidence is not uncommon.

Compassionate access

Some provinces have special access programs that re-review drugs not funded by a province and when needed by a patient. These programs help patients gain access to drugs not covered by a provincial plan or where no alternative drug is available. To access the program in BC, a patient’s doctor submits a request to the Compassionate Access Program. Each request is reviewed on a case-by-case basis for clinical reasons (e.g., to make sure the drug is safe to use) and financial reasons (e.g., to assess the potential costs to the health system because the drug is not approved for funding or is still under review for a funding decision). Refer to the Appendix for links to some compassionate access programs in Canada.

Questions to reflect upon:

• Under what conditions should expensive drugs be paid for when doctors and patients want them, even if there is little evidence of health benefit?

• What if a drug is not very expensive, but not very effective?

• Should there be a limit to compassionate access?
6. Clinical trials: knowing when a drug is safe and effective

Clinical trials are the most common source of medical evidence about a drug. Medical researchers working in laboratories at pharmaceutical companies and at universities, hospitals, and research institutions develop new drugs and then test how well they work by conducting a clinical trial. Clinical trials are designed to test whether a drug is safe to use and improves health.

When a clinical trial examines health benefit, it aims to understand if the drug is effective for the health condition it is intended to treat. Drugs may also produce side effects, such as nausea and vomiting, and clinical trials also assess these.

Medical researchers and decision makers use the results of clinical trials to decide whether the positive health benefit outweighs the potential harmful side effect(s) or is worth the extra cost of the drug when compared to currently available options. As research quality can vary, sometimes several clinical trials are needed to make this assessment.

Because a clinical trial may focus on one health outcome and/or be of limited size, it may not be designed to detect additional adverse or unexpected health outcomes. Doctors, patients and scientists continue to monitor and evaluate a drug’s safety and effectiveness even after it has been approved for use.

Sometimes a new clinical trial is conducted on an already approved drug because of unanticipated side effects or benefits. Some drugs may be recalled because of long-term side effects.

Questions to reflect upon:

- What are your views on improving overall survival (lengthening life) or improving quality of life as goals for treating cancer?
- Should the severity of health condition — that is, whether the cancer is curable or non-curvable — or a patient’s age matter in decisions about funding cancer drugs?
Evaluating safety

Clinical trials evaluate different aspects of drug safety. For example, clinical trials check for any possible damage or harm to participants through blood tests and X-rays and by checking organs like the kidneys, heart and lungs. They also check how often “serious adverse events” happen, like hospitalization, disability, and death.

Evaluating effectiveness

All phases of clinical trials look for signs of effectiveness by measuring certain outcomes. Some examples of these effectiveness outcomes are:

- **Overall survival**: the time from when a participant starts a trial to death
- **Progression-free survival**: the time from when a participant starts a trial to when the disease worsens
- **Recurrence-free survival**: the time from when all signs and symptoms of the treated disease are gone to when the disease returns
- **Tumour response**: change in the size or extent of the tumour being treated
- **Quality of life**: a patient’s or patient representative’s self-reported information about changes in physical, psychological, social, and emotional well-being
7. Drug costs: price and value

Drug pricing

The goal of medical research is to create and study new treatments to improve people’s health. It takes considerable time and money to develop new treatments. Before a drug is put into clinical trials, it has been developed by chemists and biologists in laboratories and then tested using animals. Generally, it takes nine years to bring a drug from early development through clinical trials to approval by Health Canada. It will take on average another two years for the drug to be approved for funding at the provincial level and thus placed on the province’s drug formulary.

According to Rx&D, which is an association of research-based pharmaceutical companies in Canada, only 20% of drugs that are effective enough to be tested in clinical trials make it to market, let alone receive approval for funding (see Useful Resources at the end of this booklet for a link to Rx&D’s website). Most drug companies finance their operations through shareholders who take the risk of investing money in exchange for a profit. Canada permits drug patents to last eight to 10 years, after which time a generic drug can be manufactured.

Provinces that purchase drugs in Canada negotiate with pharmaceutical companies that manufacture and supply drugs. The price of patented drugs in Canada is regulated and monitored by the Patented Medicine Prices Review Board. The Review Board acts as a regulator to ensure that the price charged by manufacturers for patented medicines isn’t excessive. Pharmaceutical companies must comply with the Review Board’s Guidelines, including lowering prices and offsetting excess revenues if the price of a patented drug appears to be excessive.

Getting value for money

Provincial governments want good value for taxpayers’ money. They consider a variety of factors when deciding about drug funding. The costs they consider include: the price of the drug, any related costs (such as hospital days, physician hours, tests, etc.), and whether the new drug is more effective than the current treatment for the same health condition. Sometimes input from patients and the public are considered in these decisions.

Researchers conduct cost-effective analyses to evaluate the relative costs and effectiveness of a new drug when compared to the standard drug.

DID YOU KNOW?

In 2009, the Patented Medicine Prices Review Board issued a Notice of Hearing to Eli Lilly Canada Inc., which agreed to reduce drug prices and make payments of over $15 million to the government of Canada “to offset any alleged excess revenues received” in relation to selling a treatment for Attention Deficit Hyperactivity Disorder at prices judged to be excessive. (see http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1440).
used to treat the same disease. The effectiveness of the drug on patients is usually determined through clinical trials and can be measured in terms of extension of life, their quality of life while on the drug, slowing the progression of the disease, and so forth. For example, some patients may feel less sick with one chemotherapy treatment than with another treatment.

Questions to reflect upon:

• What is the appropriate role of cost as a factor in whether Canadians have access to cancer treatments?

• Are there any steps you would like provinces to take to get better value for the drugs they fund?
8. What is the public’s role in drug funding decisions?

In Canada, sometimes members of the public and patients are involved in the drug funding recommendation process. Generally, patient input is more commonly sought in funding recommendations than public input. This is because patients have direct experience with the illness or disease and treatment benefits and side effects. They can also provide interpretations of what quality of life means to them, which can be different from the formal research assessments done in clinical trials or what people in better health can understand.

At the national level, the pan-Canadian Oncology Drug Review (pCODR) includes input from patient advocacy groups in their review of a specific cancer drug or type of cancer. Patient advocacy groups submit their input, which is then incorporated into the reports being written by the economic guidance panel and the clinical guidance panel. This input is also sent directly to pCODR’s expert review committee. Two patients sit on pCODR’s expert review committee.

pCODR notifies registered patient groups via email subscription when a cancer drug is submitted for review and the deadline date for providing input. Patient groups can provide input on the initial review of the drug or provide feedback after pCODR makes its initial recommendation. Members of the general public are not part of pCODR’s drug review process.

For non-cancer drugs at the national level, the Canadian Agency for Drugs and Technologies in Health (CADTH) involves patient groups in their drug review process. Submitted patient group input is forwarded in its original format and also collated and forwarded to the expert review committee to consider along with the clinical and economic information when making the recommendation. CADTH posts the name of any pending or received drug submissions—including what the drug is intended to treat and the deadline date for providing input—on its website and through email subscription. Only patient groups can provide written input using a template provided on CADTH’s website.

CADTH’s expert review committee has two members of the general public. Members of the public can apply to sit on the expert review committee if a vacancy arises. CADTH posts vacancy notifications on its website and through email subscription. All members of the expert review committee are appointed by the CADTH President and CEO.

Questions to reflect upon:

- How could the current involvement of patients and the public in the drug funding recommendation process be improved, or is it adequate?
- What type of public and patient input is appropriate?
Canadian provinces may also have opportunities for patients and/or the public to provide input on drug funding recommendations. In BC, patients, caregivers and patient groups can provide input to the review process for non-cancer drugs by completing an online questionnaire (see the Appendix for the BC Ministry of Health link). The review of cancer drug submissions is undertaken by the BC Cancer Agency. There is no formal mechanism to involve patients or the public in the cancer drug funding recommendation process in BC.

9. Summary
Making good decisions about funding cancer drugs is challenging. This booklet is intended to provide a general background to the topic of funding for cancer drugs in our public health-care system. While the booklet includes a variety of viewpoints and information, it does not cover all possible viewpoints and information on priority setting and oncology drugs in Canada. The hope is that it will stimulate ongoing reflection on this topic and contribute to a wider public dialogue on it.
10. Glossary

**Advisory committee** is a committee made up of individuals with different expertise and perspectives on the drug under consideration, including patients who have experienced the health condition for which the drug is intended. Advisory committees provide advice—in the form of recommendations—to decision makers.

**Clinical trials** are the most common source of medical evidence about a drug. They are used to test when a drug is safe to use and if it produces health benefits. They also check how often serious adverse events happen, like death, hospitalization and disability.

**Cost-effectiveness analysis** is a type of economic evaluation. It evaluates costs in relation to the effectiveness of the new drug when compared with the standard drug to treat the same disease.

**Decision maker** may be the Minister of Health for the province, the head of a hospital, or a cancer agency administrator. They are responsible for making decisions about funding drugs and other health services in their province. They base their decisions on advice from special advisory committees and consider costs, public values, and whether the drug or service is affordable and the decision is fair.

**Deliberative public engagement** brings together members of the public to learn about important issues, consider various policy options, and work together to make recommendations for policy-makers. A deliberative public engagement recognizes that citizens should have an opportunity to participate in policy matters that affect them.

**Disinvestment** is the process of partially replacing an older, less effective drug with a new drug. Disinvestment may also occur when a drug no longer provides enough health benefit to justify the cost and must be reassessed. Disinvestment rarely involves the refusal or total withdrawal of funding for a drug. Instead, disinvestment usually occurs by narrowing a drug’s scope of use. Disinvestment is part of priority setting.

**Effectiveness outcomes** describe the results of clinical trials that test how well a drug works (i.e., how effective it is). Different clinical trials will be set up to measure one or more—but not all—effectiveness outcomes. Some examples of effectiveness outcomes in clinical trials for cancer drugs are tumour response, overall survival, recurrence-free survival and quality of life.

**Health benefit** refers to the effectiveness of a drug for the health condition it is intended to treat. Health benefits are measured in clinical trials. Some health benefits are improved quality of life, increased length of life, a reduction in tumour size, and less nausea or fatigue.

**Priority setting** in health care refers to the process of making decisions about what programs, drugs, and health services to support when there aren’t enough resources to support all of them.

**Public drug formulary** is a list of drugs and drug products that are covered by a province’s public health plan. Not all drugs approved for use by Health Canada are listed on a province’s public drug formulary.
Quality of life is related to a person’s physical, psychological, social, or emotional well-being. Quality of life can include a reduction in well being, including chronic illness and death. It also relates to positively valued aspects such as happiness. Quality of life is also a way of measuring the effectiveness of a drug tested in a clinical trial.

Quantity of life is the length of an individual's lifetime measured by days, months, or years. It is an objective measure because its valuation is not dependent on an individual's personal perspective.

Trade-off means that the resources — e.g., people, time, money, experience — used in one place can't be used in another place at the same time. Trade-offs are part of priority setting when resources are limited.

Uncertainty in health-care priority setting describes a situation when decision makers don't have clear-cut evidence to work with. For example, different clinical trials for the same drug might measure different effectiveness outcomes, where one outcomes isn't clearly “better” than the other outcome and yet a fair funding decision must be made.
11. Useful Resources

Canadian Agency for Drugs and Technology in Health (CADTH). www.cadth.ca


BC Ministry of Health. www.gov.bc.ca/health

Health Canada. www.hc-sc.gc.ca


Pan-Canadian Oncology Drug Review (pCODR). www.pcodr.com

12. Appendix

Examples of organizations in Canada that accept patient and/or public input on health-care decisions are:

BC Ministry of Health:  
www.health.gov.bc.ca/pharmacare/yourvoice/

BC's Community Engagement Advisory Network:  
www.vch.ca/get_involved/community-engagement/community_health_advisory_committees/cean/cean

Canadian Agency for Drugs and Technologies in Health (CADTH) Canadian Drug Review process:  
www.cadth.ca/en/products/cdr/

The Pan-Canadian Oncology Drug Review (pCODR):  
www.pcodr.ca

pCODR Patient Engagement Guide:  

Ontario's Committee to Evaluate Drugs:  

Ontario's Citizen's Council:  

Quebec's Consultation Forum:  

Two examples of compassionate access programs in Canada are:

The BC Cancer Agency's Compassionate Access Program:  
www.bccancer.bc.ca/HPI/ChemotherapyProtocols/default.htm

Ontario's Exceptional Access Program  
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