



Patented Medicines Prices Review Board: Draft Guidelines Consultation

Canadian Cancer Society Submission

February 14, 2020

The Canadian Cancer Society (CCS) appreciates the opportunity to participate in the dialogue related to the draft guidelines prepared by the Patented Medicine Prices Review Board (PMPRB) in order to address the recently amended *Patented Medicines Regulations*. Our submission highlights some key issues from a patient perspective versus providing details on the technical details of the proposed changes to the guidelines.

CCS is pleased that the PMPRB is working to improve the affordability of medications, including oncology drugs, for all Canadians. However, we would like to be assured on how these changes will potentially affect patient access to a broad range of existing and emerging effective treatment options and any anticipated impact on advancing scientific novelty and access to clinical trials. In this submission, we outline key areas the PMPRB should consider to ensure that access to advanced cancer treatment options are not compromised as the amendments are implemented so that we can all continue to help people with cancer thrive.

As a member of the Health Charities Coalition of Canada (HCCC), we endorse their submission and consider ours a complement in this consultation.

About us

The Canadian Cancer Society (CCS) is national community-based organization of volunteers whose mission is the eradication of cancer and the enhancement of the quality of life of people living with cancer. Our vision is to create a world where no Canadian fears cancer. Our collective includes people living with cancer, their families and friends, healthcare teams, donors, researchers, scientists and CCS staff and volunteers. With the help of hundreds of thousands of people that CCS brings together, we are a force-for-life in the face of cancer.

As Canada's largest health charity, we fund world-class research, advocate for strong health policy, and help people with cancer and their families by providing evidence-based information on cancer-related issues.



Background

Cancer is a disease that affects many people; it is estimated that about 1 in 2 Canadians will develop cancer in their lifetimes and 1 in 4 will die of the disease. In 2019, there were an estimated 220,400 new cancer diagnoses and 82,100 deaths from cancer in Canada.¹ With cancer projected to increase by 2042, cancer is the single most serious health challenge facing our aging society. Canadians rely on our world-class healthcare system where high-quality treatments are accessible to all patients.

Over the past two decades, cancer treatment options have significantly improved, with cancer drugs playing an essential role to greatly improve health outcomes and quality of life for people living with cancer. The latest cancer innovations – precision medicine, targeted biological treatments, immunotherapy, radiation therapy, chemotherapy, robot-assisted surgery – have led to improved outcomes for people living with cancer. Cancer treatments work in different ways to destroy cancer cells, stop them from spreading or slow down their growth. Medicines are also being used to lessen, or relieve, side effects of cancer or its treatment. The net survival for people diagnosed with cancer has significantly increased as a result of advances in cancer treatment, diagnostics and care.

Today, over 60% of Canadians diagnosed with cancer will survive at least five years after their diagnosis. In the 1940s, survival was about 25%.^{Error! Bookmark not defined.} Despite major breakthroughs in cancer treatment, there are significant challenges in cancer care that need further research and development. The Canadian Cancer Society is seeking assurance from the PMPRB that the proposed guidelines will improve health outcomes for Canadians.

Access to cancer treatments

The Canadian Cancer Society believes that all Canadians should have access to cancer treatments without financial hardship. While CCS strongly supports the PMPRB in its efforts to protect consumers from excessive pricing, CCS is concerned that the proposed guidelines may substantially affect access to medications and affect the future of new treatments to come into Canada, including oncology drugs.

CCS fears the changes will reduce the list and net prices down to the point where pharmaceutical companies may not bring new medicines to Canada. This may lead to reduced access for new cancer medicines by years or may not get launched at all. As a result, people living with cancer may be affected significantly if the prices are set at a level that makes Canada an unfavourable place for market entry.

It can be extremely difficult for a person living with cancer and their family members to know that a cancer medication may be accessible in the global market, but not available in Canada. More often than not, people living with cancer have a limited amount of time and are unable to wait for prolonged periods of time for a medication.² For example, some patients with breast cancer require hormone therapy before their surgery. If this is not delivered within a month, it can lead to adverse health outcomes. We want to ensure that the reforms will not negatively affect access to medications and clinical trials for patients undergoing cancer treatment in Canada. We would like the PMPRB to ensure risk mitigation strategies are in place to protect patients from access-related challenges.

¹ Canadian Cancer Statistics Advisory Committee. Canadian Cancer Statistics 2019. Toronto, ON: Canadian Cancer Society; 2019. Available at: cancer.ca/Canadian-Cancer-Statistics-2019-EN (January 15 [2020]).

² Simmons CE. The changing role of neoadjuvant therapy in breast cancer: Considering systemic treatment for patients with operable as well as inoperable disease. *British Columbia Medical Journal*. 2018 Mar 1;60(2).



At CCS, we are committed to improving and saving lives, continuously seeking ways to prevent cancer, diagnose early and treat successfully to create a world where no Canadian fears cancer. Accordingly, we are the country's largest national charitable funder of research into all types of cancer to ensure people living with cancer can access the treatments they need. CCS wishes to partner with the government to ensure that people with cancer are at the centre of this important dialogue.

Research in cancer treatment

Advanced cancer technologies, strategies and services offer opportunities to save, improve and extend the lives of thousands of people diagnosed with cancer every year. A broad collection of incentives and disincentives can influence the actions of various organizations involved in healthcare.

We believe it is important to foster an environment in which cutting edge cancer research is sustainable. Accordingly, as the largest national charitable funder of research, CCS invests in the best research across 100+ types of cancer to give us a valuable sightline on all aspects of the cancer landscape and allows us to translate key learnings from one area of focus to another. In 2018, we invested \$40.4 million in the best cancer research in Canada. These funds supported 304 innovative and impactful research projects to help people with cancer live more fully. This investment also includes \$4.7 million to support the Canadian Cancer Trials Group, which conducted 122 trials involving 1,547 Canadians at 84 cancer centres across the country. These trials tested new ways to treat cancer and help people with cancer enjoy a better quality of life.

Rapid advances in healthcare outcomes over the past century would not have been possible without improvements in scientific research. These advances can deliver significant value to healthcare systems, patients and society at large. It is critical for drug discovery research to look beyond low-hanging fruit to focus on new targets and tackle cancers with an unmet need. Canada is home to world renowned hospitals, universities and researchers that are conducting strong clinical research. This infrastructure must be supported in order to ensure continued high-quality research and access to the best treatment for people living with cancer. Oncology is experiencing a significant wave of innovation that is changing the way cancer is diagnosed, treated, and monitored. Advancements in cancer treatment includes gene therapy, immunotherapy, hormone replacement therapy and targeted drug delivery systems. Access to novel therapies in a timely manner provides additional benefits to society, including improved population health and quality of life, reduced hospitalizations, increased productivity and an increasing number of jobs.³

Currently, Canadians are among priority countries worldwide that benefit from new therapies. However, CCS is concerned that PMPRB's proposed changes may lead to reluctance among manufacturers from conducting their research and development activities in Canada, which may limit Canada's ability to develop and supply high-quality medications. As such, this may slow down or limit patient access to new medicines and negatively affect patient support programs.⁴ CCS believes in establishing a system that facilitates the implementation of novel interventions into health practice. Without this, the result of the research made possible by the generosity of Canadians will not be available to Canadians.

³ Hassett KA. Price controls and the evolution of pharmaceutical markets. July 2004. www.who.int/intellectualproperty/news/en/Submission-Hassett.pdf. Accessed October 2, 2014.

⁴ Kanavos P, Sullivan R, Lewison G, Schurer W, Eckhouse S, Vlachopioti Z. The role of funding and policies on innovation in cancer drug development. *ecancermedalscience*. 2010;4.



Next steps

The benefits of advanced research cannot be realized unless the healthcare system and patients can use the new technology optimally and sustainably. As such, it is important to collaborate between all key stakeholders, including patient organizations to ensure patients remain at the centre of discussion. Our vision to create a world where no Canadian fears cancer, is only achievable if we work collectively with people united by the same goals.

CCS recognizes the complexity in balancing issues related to affordability and accessibility. However, PMPRB should ensure all stakeholders in the Canadian medication review and approval process, including manufacturers, distributors, regulators, evaluators and payers are able to contribute meaningfully. It is only through collaboration that we will be able to achieve our shared goals of making new treatments available and accessible at an affordable price for patients and the healthcare system. PMPRB should also be transparent about its processes, and provide key stakeholders including the Canadian Cancer Society with evidence that supports the amendments to the guidelines.

CCS proposes that the implementation of the new *Patented Medicines Regulation* be undertaken using a phased approach, starting with the application of the updated comparator countries to help achieve affordable prices for patients and health systems, and delay or reconsider the use of economic factors. We request the data used by the PMPRB to develop the proposed regulations, guidelines and analysis, so that we can be assured that no person with cancer will be worse off as a result of the changes to the guidelines.

In conclusion, new approaches are required to ensure we continue to invest in ground-breaking research, while ensuring both accessibility and financial stability for patients. CCS wants to ensure that Canadians' access to new treatments and investments in scientific research remains a strategic priority.