



April 29, 2019

The Right Honourable Justin Trudeau, PC, MP
Prime Minister of Canada
80 Wellington Street
Ottawa, Ontario K1A 0A2

Dear Prime Minister Trudeau,

On behalf of Research Canada: *An Alliance for Health Discovery*, we would like to thank the Government of Canada for the important investments it has made in Canadian health research and health innovation over the past four years.

At the same time, we wanted to share with you our concerns regarding the proposed reforms to the Patented Medicines Regulations, which would significantly impact how the Patented Medicine Prices Review Board (PMPRB) establishes maximum or non-excessive prices for Canadian medicines.

The proposed PMPRB reforms threaten to undermine the government's historic investments in research and innovation, constrain an increasingly vibrant health and biosciences ecosystem and market for high-quality jobs and ultimately restrict patient access to life-changing treatments.

While PMPRB is driven by an understandable desire to ensure that medicines are affordable, Research Canada is concerned that the proposed reforms will prove unaffordable for our economy, our health system and our most vulnerable patients.

Patients and Clinical Trials

Our health system, and most importantly, patients deserve access to affordable medicines—but price is only one measure of affordability. The proposed PMPRB reforms are rooted in cost-containment, not value. As a country, we need to focus on the value innovative medicines deliver to patients, health systems and the economy, which is a recommendation advanced by the government's own Health and Biosciences Economic Strategy Table (HBEST).

If innovative life sciences companies—both global and homegrown—are forced to look to markets elsewhere in the world, Canadians will pay the price. Canada will cease to be a destination for clinical trials and product launches; among benchmark countries, Canada is second only to the U.S. in number of clinical trials, and we are consistently a priority market for new products.

The benefits of clinical drug trials are broad and undeniable. These trials often represent the very earliest access to innovative and life-saving therapies for patients and the economic advantages gained by these investments are far-reaching. However, to reap these benefits, Canada's health and biosciences companies have to have a favourable market for launching any new medicines.

While all Canadians want access to medicines at affordable prices, as an alliance of diverse interests, including those of patients, health consumer groups and the public generally, we are worried that the proposed reforms will drive drug prices so low that there will be longer delays for access to the most innovative medicines, and some may never be launched in Canada. For many patients, any significant delays in access to new drugs can mean the difference between life and death. Promising drugs may be the terminally ill or rare disorder patient's last and only chance. If vulnerable Canadians will not have access to the innovations they need, the principles of equitable, high-quality care for all Canadians will be put in jeopardy.

A Thriving Health and Biosciences Ecosystem

A thriving health and biosciences ecosystem depends on strong, predictable demand for innovation by health systems and consumers. The Ministry of Innovation, Science and Economic Development recently produced the HBEST Report with recommendations aimed at advancing the health and biosciences enterprise in Canada, providing a unique opportunity to drive high-skills economic growth, while also improving Canada's healthcare system through innovation. Research Canada applauded these recommendations because they set forth the right market conditions or "pull" that drives innovation; however, the proposed series of pricing reforms through PMPRB are essentially countermeasures that not only undermine the government's HBEST recommendations, but will compel companies to retrench—costing our economy and limiting access to high-paying, knowledge-based jobs.

Canada's pharmaceutical industry employs 34,000 highly skilled workers and directly contributes more than \$1 billion into this country's research and development. In 2017, a new analysis was published by the International accounting firm of Ernst & Young concluding that the pharmaceutical industry reinvested an estimated total of 9.97% of gross patented product revenue into R&D in 2016. Research Canada is deeply concerned that the proposed PMPRB reforms, which are likely to cost industry \$26.1 billion over 10 years, will significantly impede these investments.

Employing Academe's Deep Talent Pool

While Research Canada welcomed the \$114 million over five years in scholarship awards through the Canada Graduate Scholarship Program in Budget 2019, without a robust and well-supported health and biosciences industry, the deep talent pool emerging from Canada's academic institutions, in which this government recently invested, will not find jobs, jeopardizing efforts to expand and attract capital, open markets and supply chains, and build strong local ecosystems. The problem is that less than 20 percent of current post-doctoral students in Canada will secure tenure-track faculty positions. This has resulted in a "hypercompetitive job market" for this highly-qualified future generation who are increasingly looking for employment outside of academe. A vibrant health and biosciences sector supported by government policies that enhance the sector's capacity to do business in Canada can open doors to whole new career options for these post-doctoral students, including careers in science.

Canada's health and biosciences companies work in a space bombarded by rapid scientific and technological change; global political, economic and financial uncertainty; and within a complex policy environment. They are looking to government to play a strong national leadership role and adopt a consistent "whole-of-government" approach to health and biosciences innovation.

A functional innovation system is about effecting the right balance of push and pull at each stage of the innovation cycle. This balance is mediated by the appropriate allocation of roles and investments among key stakeholders in government, academia, industry, the non-governmental sector and patient and health consumer groups. Industry brings technical knowledge, expertise in regulatory submission, industrial capacity and global reach while patient groups bring information and experiences concerning their conditions and diseases—data that informs medical research and delivers more patient-centred treatments and services.

Incomplete Community Engagement

Research Canada is concerned that the serious deficiencies inherent in these reforms reflect a community engagement process that was both perfunctory and incomplete. It is incumbent upon government when making significant changes to policies that will directly impact stakeholders, that these stakeholders are engaged meaningfully in the policy-making process. It is questionable as to whether the health and biosciences industries and patient representatives who participated on the PMPRB Steering Committee on Guidelines Modernization were meaningfully consulted in the process leading up to the proposed PMPRB reforms and whether the process was an evidence-based one.

Patients play a vital role in the national discussion regarding new medicines. In recent years, many health and biosciences companies have developed new ways to incorporate patient insights and to collaborate with patients and patient organizations in a transparent and ethical way. This has led to better trials, better engagement, better communication through the entire life cycle of medicines and ultimately, better patient outcomes. Industry and patient organizations are committed to improving collaboration and building trust across the entire spectrum of stakeholders engaged in the health innovation ecosystem.

In the absence of meaningful community engagement in this PMPRB reform consultation, we run the risk of these reforms not achieving the cost-containment objectives to which they aspire and almost certainly harming patients and the health and biosciences ecosystem in the process.

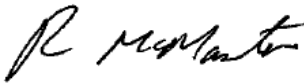
In the end, if the goal of these pricing reforms is to save money, it is questionable whether the government will be successful. As Dr. Jason Field, President and CEO of Life Sciences Ontario recently pointed out in an article in the Financial Times: "Patented medicines represent less than seven per cent of total healthcare spending, yet are one of the areas with the most added value to our health system—reducing hospitalizations and other costly complications of disease and delivering long-term health-system savings in the process."

Research Canada is requesting that the Government of Canada reconsider the proposed PMPRB reforms by putting in place a new, more integrated and comprehensive process in support of the full innovation ecosystem that brings all key stakeholders to the table. The success of Canada's system of innovation will ultimately reflect the degree to which we nurture the dynamic relationships among key stakeholders and balance the forces of push and pull across the full innovation cycle through sound, evidence-based policymaking.

In the absence of hard evidence, meaningful consultation with the health and biosciences sector and patient groups, and a potentially devastating outcome for the most vulnerable Canadians who may not have access to life-saving medicines, we call upon the Government of Canada to do the right thing and put Canadian patients first.

As a multi-stakeholder alliance, we welcome the opportunity to work with the Government of Canada to discuss our community's concerns and develop sensible reforms that enable a balanced, whole-of-government approach to health and biosciences policy in Canada.

Sincerely,



Dr. Robert McMaster
Chair



Dr. Ryan Wiley
Policy Advisor and Chair,
Policy Engagement Committee



Ms. Deborah Gordon-El-Bihbety
President and CEO

cc. The Honourable Navdeep Bains, Minister of Innovation, Science and Economic Development
The Honourable Kirsty Duncan, Minister of Science and Sport
The Honourable Ginette Petitpas Taylor, Minister of Health
The Honourable Bill Morneau, Minister of Finance