The Patented Medicine Prices Review Board's Final Guidelines

Research Canada Submission to the
House of Commons Standing Committee on Health (HESA)

Summary of Recommendations

Recommendation 1: That the federal government consider the broad impacts of the PMPRB reforms on the entire health research and innovation ecosystem before implementing the regulatory amendments and guidelines.

Recommendation 2: That the federal government reconsider not only the PMPRB reforms' impact on cost but also on value, as well as on patients' access to innovative medicines and clinical trials in Canada.

Recommendation 3: That the federal government consider the PMPRB reforms' potential impacts on employment for the next generation of highly skilled researchers, and on its own investments into this group.

Recommendation 4: That the federal government defer implementation of the PMPRB reforms until it has concluded a more comprehensive process in support of the full health research and innovation ecosystem, bringing all key stakeholders who will be impacted by these reforms to the table.

Introduction

Research Canada would like to thank the Committee for the opportunity to submit our comments regarding the Patented Medicine Prices Review Board's (PMPRB) Guidelines for the Patented Medicines Regulations (PMR). We commend the Committee's work to continue advancing Canada's health interests despite the severe contingencies imposed by the COVID-19 pandemic. The pandemic and Canada's focus on recovery only highlight the need for a regulatory environment that encourages and supports health innovation, giving all of the people of Canada access to high quality medicines, including to the novel therapies and vaccines we hope will serve as potential solutions to this crisis.

Why We Are Commenting

As an organization dedicated to advancing health research and innovation in Canada, we have watched the development of the PMPRB reforms with great interest. We represent academic health science centres, universities, colleges, research and health professional associations and societies, health charities, Networks of Centres of Excellence, biopharmaceutical, medical device and biotechnology organizations. Our advocacy, however, is on behalf of Canada's entire health research and innovation ecosystem in which these stakeholders all play a vital role. As such, we do not intend to comment on specific aspects of the guidelines but, rather, we intend to draw the Committee's attention to the vital importance of asking – and knowing – how the guidelines may impact the health research and innovation ecosystem as a whole. Our expertise is in understanding and communicating how policy changes in one area, such as the PMPRB reforms, can have ripple effects throughout Canada's health research and innovation ecosystem.

Reforms? Yes, but with Caution

We support the fundamental responsibility of the federal government to ensure that the price of medicines reflects the value they deliver to patients and health systems, and that this price supports affordability and accessibility for all the people of Canada. Reforms to our decades-old pricing regime are needed to reflect changes in technology, healthcare delivery and value assessment. We have grave concerns, however, that these guidelines have been created as part of a process lacking broad and thorough consultation. In essence, the federal government is flying blind into the implementation of its PMPRB reforms, which include the regulatory amendments to the PMR and the PMPRB's Final Guidelines, because the question of potential impacts, intended or otherwise, has not been formally or thoroughly explored with those who will be affected, both directly and indirectly. For our part, **Research Canada is concerned that in the absence of an inclusive consultation that not just the guidelines, as the focus of the Committee's study, but the PMPRB reforms as a whole, may prove unaffordable for our economy, our health system and our most vulnerable patients**. We believe that if we do not get this right they may threaten to undermine the government's historic investments in research and innovation, constrain an increasingly vibrant health research and innovation

ecosystem and market for high-quality jobs, and will ultimately restrict patient access to life-changing treatments.

As a result, Research Canada's fourth recommendation stands out as its most important: **Research Canada recommends that the federal government defer implementation of the PMPRB reforms, which include both the amended PMR and the final guidelines until it has concluded a more comprehensive process in support of the full health research and innovation ecosystem, bringing all key stakeholders who will be impacted by these reforms to the table.**

Understanding Canada's Health Research and Innovation Ecosystem: Why Caution is Needed

A functional health research and innovation ecosystem must balance the *push* forces of knowledge creation with the market forces that *pull* ideas and technologies toward health application and impact. Such an ecosystem reflects society's willingness to assume the *risk* of creating knowledge with uncertain future benefits, and its appetite to harness and *reward* the fraction of knowledge output that holds tangible social and economic promise.

Government, academia, industry, not-for-profit organizations, patients and research users have pivotal roles to play at every stage. Public policy, meanwhile, establishes the contexts in which the ecosystem flourishes or falters. It is therefore crucial that those proposing and enacting policy thoroughly understand the elements of an ecosystem in balance and how particular proposals may affect this ecosystem so that they can create policies that support Canada's overall innovation objectives.

The pharmaceutical industry directly contributes $1 billion into homegrown research and development[1] and employs 34,000 highly skilled workers. It is an important source of jobs for the highly skilled university graduates in whom our government is investing. A 2017 analysis by Ernst & Young concluded that the pharmaceutical industry reinvested an estimated 9.97% of gross patented product revenue into R&D the previous year.[2] Research Canada is concerned that the PMPRB reforms, which are likely to cost industry $26.1 billion over 10 years,[3] may significantly impede these investments.

For a counterexample, we would point the Committee to the Health and Biosciences Economic Strategy Table (EST) Report of 2018, one of six ESTs initiated by the Minister of Innovation, Science and Economic Development in 2017. Its recommendations, aimed at advancing the health and biosciences enterprise in Canada, form the roadmap to ensuring this industry not

[1] Innovative Medicines Canada. Retrieved from website: http://innovativemedicines.ca/innovation/industry-impact/
[2] Ernst & Young. *Innovative Medicines Canada: Data Analytics and Members' Economic Footprint and Impact in Canada*. Retrieved from: http://innovativemedicines.ca/wp-content/uploads/2017/10/20171030_EY-REPORT_IMC_FINAL.pdf
[3] PDCI Market Access. *Proposed Amendments to the Patented Medicines Regulations: A Critical Appraisal of the Cost-Benefit Analysis*. Retrieved from: https://www.pdci.ca/wp-content/uploads/2018/01/20180129_PDCI-Critical-Assessment-PM-Regs-Amendments_Report-Final.pdf

only has a future in Canada but is doubled in size to $26 billion in annual exports; a 180-degree contrast to the scenario that may play out under the new PMR and guidelines, as currently conceived. Research Canada applauded the Health and Biosciences EST's recommendations because they set forth the right market conditions, or "pull," that drive innovation. These recommendations require policies to incentivize Canadian healthcare entities to adopt value-based Canadian innovations, as well as a viable regulatory landscape, free of irritants and in line with other jurisdictions, that will create the kind of stable, predictable environment, which encourages innovation. We ask why the federal government would proceed in the direction of implementing the PMPRB reforms when these seem to contradict the direction recommended by its own innovation ministry's report?

Recommendation 1: *That the federal government consider the broad impacts of the PMPRB reforms on the entire health research and innovation ecosystem before implementing the regulatory amendments and guidelines.*

Limiting Patients' Access to Cutting Edge Medicines, Diminishing Canada as a Site for Clinical Trials

Our health system and, most importantly, patients deserve access to affordable medicines—but price is only one measure of affordability. The PMPRB reforms are rooted in cost-containment, not value. As a country, we need to focus on the value that innovative medicines deliver to patients, health systems and the economy, a recommendation advanced in the Health and Biosciences EST's Report. If innovative life sciences companies—global and homegrown—are forced to look to markets elsewhere in the world, the people of Canada will pay the price.

Among those costs, Canada may cease to be a destination for clinical trials and product launches; globally, Canada is fourth in number of clinical trial sites, conducting 4% of global clinical trials[4], 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. The economic advantages gained by these investments are far-reaching. However, to reap these benefits, Canada's health and biosciences companies must have a favourable market for launching new medicines.

While all of the people of Canada 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, in the absence of evidence to the contrary, that the proposed reforms will drive drug prices so low that there will be longer delays for access to the most innovative medicines. Some may never be launched in Canada. Our concern is only heightened in this time of COVID-19 when so many nations are in the hunt for novel treatments and vaccines and when an attitude of partnership with industry is critical. This concern is not new; any significant delays in access to new drugs for an array of illnesses and conditions can mean

[4] Government of Canada. *Clinical trials environment in Canada.* Retrieved from website: https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01774.html

the difference between life and death for some patients. If vulnerable patients will not have access to the innovations they need, the principles of equitable, high-quality care for all of the people of Canada will be put in jeopardy.

Recommendation 2: *That the federal government reconsider not only the PMPRB reforms' impact on cost but also on value, as well as on patients' access to innovative medicines and clinical trials in Canada.*

Shutting the Employment Door on Canada's Next Generation of Researchers

The federal government has made historic investments into research and highly skilled researchers, beginning with its nearly $4-billion announcement in Budget 2018, recognizing the important role that fundamental science plays in the development of our economy and our nation. In Budget 2019, Research Canada welcomed the announcement of $114 million over five years for scholarship awards, through the Canada Graduate Scholarship Program. Yet, without a robust and well-supported health and biosciences industry, the deep talent pool emerging from Canada's academic institutions in which this government has invested will likely struggle to find jobs, jeopardizing efforts to expand and attract capital, open markets and supply chains, and build strong local ecosystems. It is estimated that less than 20 percent of current post-doctoral students in Canada will secure tenure-track faculty positions.[5] This has resulted in a "hypercompetitive job market" for this highly qualified future generation, leading them to increasingly look 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. Our human capital investments have a better chance of remaining in this country, contributing to Canadian innovation – for or the benefit of patients across Canada and to Canada's innovation economy – if the Canadian job market has a healthy health and biosciences sector.

Recommendation 3: *That the federal government consider the PMPRB reforms' potential impacts on employment for the next generation of highly skilled researchers, and on its own investments into this group.*

Why Speaking to Those Who Will be Impacted is So Important

Research Canada is concerned that the serious deficiencies inherent in the PMPRB reforms reflect a community engagement process that has been perfunctory and incomplete. It is incumbent upon government, when making significant changes to policies that will directly impact stakeholders, that these stakeholders are meaningfully engaged 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

[5] The Canadian Association of Postdoctoral Scholars. *The 2016 Canadian National Postdoctoral Survey Report*. Retrieved from: https://www.caps-acsp.ca/wp-content/uploads/2016/11/2016_CAPS-ACSP-National_Postdoc_Survey_Report.pdf

Modernization were meaningfully consulted in the process leading up to the reforms and whether the process was an evidence-based one. Also, other stakeholders whose sectors will be affected by the implementation of these reforms, such as academic health science centres, universities and colleges should have been gainfully engaged in the process. Representatives from the Canadian Organization for Rare Disorders and Myeloma Canada, who were two of the three patient representatives on the Steering Committee, voiced their frustration in a letter to the Prime Minister in April 2019.[6] They called the Steering Committee's process "infuriating" and that they were "limited to policy directions already decided by PMPRB staff," with limited data and analyses to validate the policy and guidelines. They also predicted that based on what they did know, the reforms would result in many new therapies not being available in Canada.

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 research and innovation ecosystem.

Academic health science centres in Canada account for nearly $3 billion of this country's biomedical sciences research activity[7] and employ more than 20,000 highly skilled researchers and staff in Ontario alone. AHSCs are home to specialized core research and healthcare facilities, making them critical institutions in the development of vaccines and treatments, the rollout of clinical trials related to COVID-19 and other ongoing health concerns impacting the people of Canada. Yet, their future was put at risk recently due to the suspension of pre-existing work to re-focus capacity on COVID-19, which caused a sudden and substantial loss of funding from industry and charitable research sponsors. We are grateful that the federal government recognized the importance of extending emergency wage subsidies to personnel working in this sector, which is largely supported by third-party funders; however, this experience underscores the impact that industry's withdrawal from clinical trials as a possible result of these reforms would have on a critical sector within Canada's health research and innovation ecosystem. It is why HealthCare*CAN*, a national organization representing the sector, co-signed a letter along with other National Partners to the Prime Minister[8] asking the government to defer implementation until an inclusive and comprehensive engagement of all stakeholders impacted by these reforms could be undertaken. The potential for negative impacts for their respective sectors stemming from the implementation of these reforms also prompted Colleges and Institutes Canada and the Health Charities Coalition of Canada to co-sign this letter alongside Research Canada and HealthCare*CAN*.

[6] Letter to the Prime Minister of Canada from Dr. Durhane Wong-Rieger and Martine Elias, April 8, 2019.
[7] Research InfoSource. Inc. News release: "Hospital Research Spending Subdued." Nov. 14, 2019.
[8] Letter to the Prime Minister of Canada from Denise Amyot (Colleges and Institutes Canada), Connie Côté (Health Charities Coalition of Canada), Paul-Émile Cloutier (HealthCare*CAN*) and Deborah Gordon-El-Bihbety, Research Canada, September 2020.

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

Recommendation 4: *That the federal government defer implementation of the PMPRB reforms until it has concluded a more comprehensive process in support of the full health research and innovation ecosystem, bringing all key stakeholders who will be impacted by these reforms to the table.*

A Delicate and Critical Time

The COVID-19 public health crisis has shed light on the importance of a collaborative, balanced and thriving health research and innovation ecosystem for pandemic preparedness. This has been a moment of enormous challenge, but also of enormous success. The research community in Canada has been able to respond quickly and effectively to COVID-19 precisely because of the interrelationships between sectors that exist in our health research and innovation ecosystem, of which the health and biosciences sector is an essential partner. These relationships, however, depend on Canada's commitment to keeping this ecosystem in balance.

We have also seen that other health challenges do not disappear during a pandemic; indeed, many chronic diseases and mental health issues have been exacerbated by COVID-19. These combined demands place an inordinate amount of pressure on manufacturers in many industries that have been struggling to manage the pandemic's growing impact on their supply chains, reinforcing the importance of developing resilient supply chains that anticipate, react to and recover from these unexpected events.

Given these ongoing and emerging health threats, it is of vital importance that we preserve the integrity of the health research and innovation ecosystem and the health and biosciences sector and protect the considerable investments the Government of Canada has made to advance health research in recent years. Our health security and future preparedness as a country demands research and development to advance preventative, therapeutic and diagnostic health technologies and tools that will help to both improve and protect the health of all of the people in Canada.

Conclusion

There is no such thing as an overnight success. Successful commercialization of innovation by Canadian-grown companies is the result of a fully supported ecosystem of people, ideas, policies and efforts leading to the creation and translation of research concepts into health impact. When only some stages are supported while others are neglected or impeded, the effects reverberate throughout the ecosystem. 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 and their partner components of the health research and innovation ecosystem are looking to

government to play a strong national leadership role and adopt a consistent "whole-of-government" approach to health and biosciences innovation.

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. By deferring implementation of both the amended PMR and final guidelines and creating a space for deeper dialogue, the federal government will allow all of us to work together to get these reforms right and avoid compromising the integrity of Canada's health research and innovation ecosystem at a time when it is so acutely needed by the people of Canada. We thank the Committee again for this opportunity to share our insights and concerns.

About Research Canada: Research Canada is a national alliance dedicated to advancing health research and health innovation through collaborative advocacy. Our mission is to improve the health and prosperity of all of the people of Canada by championing Canada's global leadership in health research and innovation.