



2022 Proposed Updates to the Patented Medicine Prices Review Board (PMPRB) Guidelines

Research Canada Submission to the PMPRB

By: Research Canada

Our Recommendation

The implementation of the new PMPRB Guidelines must be delayed to allow for meaningful consultation with industry, patient groups and other stakeholders.

Introduction

Research Canada would like to thank the Patented Medicine Prices Review Board (PMPRB) for the opportunity to submit our comments regarding the 2022 proposed updates to the PMPRB Guidelines. The pandemic and Canada's focus on recovery only highlight the need for a regulatory environment that encourages and supports health innovation and ensures that patients are able to access the best treatments available without delay.

As an organization dedicated to advancing health research and innovation in Canada, we have watched the development of the PMPRB reforms with great interest. Our advocacy is on behalf of Canada's entire health research and innovation ecosystem and its many stakeholders, each of whom plays a vital role. As such, we do not intend to comment on specific aspects of the guidelines, but rather we intend to draw the PMPRB'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.

THE HEALTH RESEARCH AND INNOVATION ECOSYSTEM IS Canada's network of postsecondary institutions, research hospitals, incubators, start-ups, innovative companies, investors, health charities and patient groups, each working in collaboration to advance science and develop innovative solutions to improve the health and wellbeing of all people living in Canada.

About Research Canada: Research Canada is a national alliance whose mission is to improve the health and prosperity of all Canadians by championing Canada’s global leadership in health research and innovation.

The irreplaceable role of the life sciences industry¹

The life sciences industry, which includes biopharmaceutical companies, plays a unique and irreplaceable role in a functional health research and innovation ecosystem. It contributes to basic and applied biomedical research at universities and institutes across Canada; helps Canada’s research hospitals drive drug discovery, enhance clinical services and improve patient outcomes; fuels the innovation pipeline and enhances the success of homegrown Canadian enterprises; develops talent by employing highly-skilled personnel and training the next generation of life sciences leaders; and spearheads initiatives aimed at preparing the health system for 21st century innovations.

However, persistent weaknesses in our partnership with the life sciences industry—and biopharmaceutical companies in particular—are handicapping the competitiveness of our ecosystem and compromising our ability to deliver innovations to patients. We are in a global competition for investment and Canada is slipping further from the front of the pack and becoming a global exception compared to countries like the UK and Israel, for example, which have been successful in building strong working relationships with the biopharmaceutical industry. When COVID-19 was upon them, these countries were able to quickly mobilize and secure vaccine supply for their citizens. Industry-sponsored clinical trial activity in Canada has decreased more rapidly than in other jurisdictions, impacting early patient access to medicines. The environment for global pharmaceutical companies reflects broader industrial, capital and structural barriers for homegrown companies.

If we are to position our health research and innovation ecosystem for a powerful post-pandemic future, we need to cultivate an ambitious, futureproofed policy and investment environment that supports our ecosystem as a whole and positions Canada for sustainability, growth and leadership. We need an environment that enables the critical role of the life sciences sector in advancing collaborative R&D in Canada; enlarges Canada’s share of global life sciences sector investment in infrastructure, research, training and jobs; expands and diversifies opportunities for training and employing, attracting and retaining highly-qualified personnel; accelerates the translation, commercialization and adoption of home-grown innovations; and fulfils the potential of our investments by ensuring health research and innovation enabled health care.

¹ Report of Research Canada’s Advisory Panel (2021). **Invigorating the Biopharmaceutical Sector’s Contribution to Canada’s Health Research and Innovation Ecosystem.**

Delaying the implementation of the guidelines

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, health care delivery and value assessment. We have grave concerns, however, that the 2022 proposed updates to the PMPRB guidelines, and the process by which they have been developed, are creating an environment adverse to the one Canada needs. If implemented as planned on January 1, 2023, these guidelines will mitigate the opportunity for the life sciences industry to play its critical role in advancing Canadian health research and innovation. Stakeholders across the ecosystem have raised concerns that these guidelines will make it even harder for Canadians to access new, life-saving medicines.² Currently, only 18 percent of new medicines launched globally are available to Canadians on public plans. And for rare disease patients, even the smallest delay in treatment accessibility increases the risk of major health complications.³ We *have* to get these reforms right or patients—especially those with rare diseases—will suffer.

Getting these reforms right takes time and meaningful consultation with stakeholders—including patients, researchers and the life sciences industry. The expedited timeline of this consultation period and planned implementation is inadequate for the kind of consultation that an issue as important as patients' access to medicines demands. This is why **Research Canada strongly urges the PMPRB and the federal government to defer implementation of the 2022 updates to the guidelines until it has concluded a more comprehensive process in support of the full health research and innovation ecosystem and to commit to meaningfully including in this process all key stakeholders who will be impacted by these reforms.**

Conclusion

It is disappointing to see that concerns about insufficient time and meaningful consultation with stakeholders continue to be an issue plaguing the PMPRB reforms. Two years ago, Research Canada raised many of these same concerns with the House of Commons Standing Committee on Health's study of the PMPRB's guidelines at the time.⁴ The PMPRB has a responsibility to all Canadians to engage in meaningful dialogue and to apply an approach of reasonable compromise in the discussion with all stakeholders, or else it will share responsibility in moving Canada closer

² For example: **ALS Canada**; **Canadian Organization for Rare Disorders (CORD)**; **Cystic Fibrosis Canada**; **Myeloma Canada**; **Innovative Medicines Canada**; Financial Post Opinion (November 1, 2022) **Suffer from a rare disorder in Canada? Good luck**

³ Innovative Medicines Canada. (March 17, 2021). **Meet the Patients: Biba Tinga and her family's journey with sickle cell disease.**

⁴ **Research Canada Submission to the House of Commons Standing Committee on Health (HESA)**. November 2020.

to the bottom of the pack when it comes to global investments in our industries. More importantly, the PMPRB's ultimate responsibility is to the patients who rely on their ability to access innovative and life-saving medicines. Careful consideration of all factors and input from all stakeholders is crucial when the stakes—the health and wellbeing of Canadian patients—are this high.