

## **The Impact of PMPRB Modernization Initiative on Canada's Biotechnology Ecosystem and Healthcare**

### ***Introduction***

BIOTECanada is the national industry association representing more than 230 members from across Canada. Membership includes research organizations, universities, early stage companies, investors, large multinational companies and regional life science incubators. Additionally, provincial life science and biotech organizations from each of the provinces are included in BIOTECanada's membership. The members represent a unique national network dedicated to realizing the potential of bridging world leading research into developing the solutions aimed at improving human health, mitigating impacts of climate change and securing food sustainability.

Hundreds of Canadian biotechnology companies are developing and introducing solutions to improve agriculture and nutrition, protect our environment, and provide better healthcare outcomes for many diseases. The sector is helping to fill the economic void of other industries devastated by the pandemic. As one of the country's premiere high technology performers, biotechnology continues to act as an innovation engine, a source of highly skilled employment, and a destination for investment capital. It also creates innovative technologies that lead to other industries, such as agriculture, resource management, and manufacturing, being more competitive.

### ***The Canadian Biotechnology Ecosystem***

It is the value and potential of this unique ecosystem that has driven BIOTECanada to work to address the negative impact the imminent changes to the PMPRB regulations are having and will have, on the quality of the Canadian healthcare system. These changes come at a critical time for Canada and Canadian patients. Aside from the reality of both the short term and longer-term impact of the COVID 19 pandemic, the nature of how healthcare solutions are discovered and ultimately accessed is undergoing unprecedented levels of change.


It is important for public policy addressing health care needs to also recognize the important investment catalyst role multinational pharmaceutical and biotech companies play in driving Canadian innovation. As evidenced by the global efforts to develop vaccines and therapeutics for the current pandemic, collaboration and partnership are key to the development of successful prevention and treatments. This work also reflects the changed dynamic where multinational pharma increasingly partners with start-ups to perform risky R&D work on new medicines. The traditional business model of conducting all work in-house in one company has evolved into a new paradigm of seeking aligned research platforms and co-researching and developing potential products.

As Canada looks to solving the pandemic and returning to what was considered normal, it is pretty certain the conditions for so doing will depend on having in place: efficient testing and tracing capacity; a diverse suite of anti-viral therapeutics; and, an availability and acceptance of effective vaccines. On all three, the biotech sector will play a central role in delivering solutions.

In anticipation of solutions being delivered and a return to normalcy, the governments are focused on preparing for a potential future COVID-like healthcare crisis and rebuilding the economy. In this process, there is a recognition that post-COVID some important economic sectors will be slow to return to full steam and some may never recover. Understanding this, government will be looking to other sectors to both launch the economic recovery and become economic cornerstones in the long term. The sector's ability to deliver healthcare solutions during the pandemic coupled with its economic performance over the past six months clearly demonstrates that it can support the government's objectives of preparing for future COVID-like health crises as well as begin an economic rebuild.

But the sector's ability to develop solutions and drive economic growth requires government to see the whole ecosystem. For Canada, this is a national ecosystem comprised of over 900 early stage companies as well as investors, universities, research institutes and multinational pharma and biotech companies. Accordingly, public policy for the industry needs to recognize the important role the pharma industry plays in the overall competitiveness of the Canadian biotech sector. Narrow pricing and reimbursement policy focused on driving down drug prices risks negatively altering the investment decisions of multinational companies which will create a drag on the ability to finance innovation in this country.

Understandably, as we sit amidst the uncertainty generated by COVID it can be difficult to see past the current crisis and identify a clear sight-line on longer term objectives. That said, now is exactly the time when we should be focusing on the future. The biotech sector represents an important opportunity for health security and economic growth. The government has leaned heavily on the sector through the pandemic and will in all likelihood continue to do so going forward. Accordingly, recognizing, leveraging and investing now in its multiple strengths and components including early stage companies, universities, research institutes, and large multinational companies, will create the fertile environment for biotechnology to bring high value therapeutics and vaccines to the world and generate economic growth in the process. But to realize this opportunity and deliver on its own economic and health objectives government policy will need to match the complexity of the biotech ecosystem. Policy that pushes the large multinational companies out of the ecosystem will serve only to restrain its ability to grow.



Biotechnology knowledge and development is highly moveable. Unlike resource-based industries, capital, people and ideas can move freely across the globe. Our biotechnology sector operates in a hyper-competitive and ever-changing world in a race for investment and talent, not only with biotechnology companies but a broad range of business sectors. As global forces reshape the economic landscape, Canada needs to maintain its capacity to compete at global investment decision tables. Establishing Canada as an overburdened and complex environment for accessing new medicines via clinical trials or actual product listings, is counterintuitive to attracting the attention of global research and development partners.

The biotech sector is vital for our health security and economic growth. The government has leaned heavily on the sector through the pandemic and will in all likelihood continue to do so going forward. Accordingly, leveraging and investing in the sector's multiple strengths and components, including early stage companies, universities, research institutes, and large multinational companies, will create an environment conducive to bringing high value, next-generation agricultural, health and industrial products to the world and enable the economy and healthcare system to get an early jump on recovery.

### ***PMPRB Impact on Healthcare Solutions***

The Canadian regulatory and policy environment has a vital role to play in ensuring the knowledge base supporting clinical care and patient outcomes are aligned with international practices and opportunities. As the world calls upon the industry to deliver solutions for the current pandemic crisis, public expectations for improved innovative therapies for oncology, rare disease and autoimmune disorders also continue to grow. Globally, and in Canada, the industry has developed extensive research capacity aimed at meeting these demands.

Canada has effective mechanisms in place to address the pricing of new therapies. As evidenced by the annual reports of the PMPRB itself, drug prices have been maintained at global median prices providing access to medicines at competitive levels with OECD countries. The work of CADTH/INESSS, PMPRB and pCPA all address the issue of value and pricing. Three levels of scrutiny designed to evaluate effectiveness of medicines while ensuring value for money have been providing access to clinical trials and new therapies to patients for years. These other mechanisms that make up a continuum of regulatory checks from Health Canada to pCPA that address access to new therapies and investment, will need to expedite their collective efforts in reducing regulatory barriers and time in order to maintain a level of access to new medicines and counter the negative impact these PMPRB regulations.

BIOTECanada has highlighted the serious gaps relating to the implementation of the proposed Guidelines. Strikingly, PMPRB staff have in fact admitted they themselves are not certain on how the new regulations will in fact be applied. PMPRB staff have stated that in those cases where clarity is not established on how to apply new guidelines to products, they will undertake decision making on a case-by-case basis, thereby admitting they do not know how to implement the regulations they themselves have designed and will make up decisions as they work through their reviews.

The price of a drug is but one element when evaluating a cost to the healthcare system. Focusing solely on price as the primary threshold in evaluating a new medicine negates the broader value a medicine brings to the entire system of care. The proposed policy modernization demonstrates PMPRB has diverted significantly from its risk-based approach and instead focuses on limiting access to the most innovative and breakthrough treatments or the medicines that are most successful in treating patients.

## **Conclusion**

The regulatory changes to the PMPRB were drafted in a pre-pandemic environment. Quite clearly the business and healthcare landscape has been significantly altered as a result of the Coronavirus. In this context, the new Guidelines are putting at risk Canada's standard of clinical practice, putting Canadian doctors and system of care behind in the knowledge required for the next generation of health innovation. This will certainly diminish research and investment into Canada. Clinical practice requires certainty in access to new clinical trials and therapies to build the sustainability required for the healthcare system. This is particularly relevant as we look towards medicines of the future addressing the vast unmet needs of patients with rare diseases, the pipeline of oncology therapies and vaccines, and in many cases potential cures for currently debilitating or terminal illnesses. These advancements build on an established foundation and bring with them a need for evaluation of capturing real world patient outcomes.

Coming out of the pandemic, Canada must prepare for the next health crisis and rebuild the economy. The biotech sector can play an instrumental role on both fronts. The engagement of multinational pharmaceutical and biotechnology companies is a critical component of the Canadian biotech ecosystem. While this is clearly not the purview of the PMPRB, the implications for investment in Canada are a significant concern to the pre-commercial early stage company members of BIOTECanada. There is no question that the uncertainty being created will negatively impact investment and business decisions of the multinational companies in Canada.