



Innovative Medicines Canada

2021 Federal Pre-Budget Consultation

February 18, 2021

About Innovative Medicines Canada

Innovative Medicines Canada (IMC) is the national association of 45 biopharmaceutical and vaccine companies who are working steadfastly, with Canadian governments, to address the COVID-19 pandemic.

Guided by a strict Code of Ethical Practices, we work with governments, insurance companies, healthcare professionals and stakeholders to advance the field and enhance the wellbeing of Canadians. We are committed to being valued partners in Canada's healthcare system.

IMC member companies produce the diagnostics, medicines and vaccines that will enable Canada to emerge from the global pandemic that continues to have devastating impacts on the health and prosperity of Canadians.

Recommendations

- 1. The medicines and vaccines industry calls on the federal government to join the innovative pharmaceutical industry in a roundtable discussion about the path forward to an actionable national strategy that will build a more vibrant life sciences sector and enhance patients' access to innovative new medicines. Such a strategy must address critical issues like domestic manufacturing, a more streamlined regulatory system, affordability, access for patients to drugs for rare diseases, and incentives for investment.*
- 2. Changes to the Patented Medicine Prices Review Board (PMPRB) are having a destabilizing impact on our industry at a highly sensitive time and jeopardizing patients' access to needed medicines. A fundamental rethink of this policy is required including the removal of damaging and experimental economic regulatory factors. At a minimum, the government should delay the implementation of PMPRB regulatory changes until the COVID-19 pandemic has abated.*

Rationale:

1. The COVID-19 pandemic has highlighted two fundamental truths about Canada's innovative pharmaceutical industry. One, that the industry is critical to Canadians' health and well being; and two, its relationship with government needs a dramatic re-thinking. The issue of vaccine accessibility shines a bright light on both points. We must do more to strengthen pharma's presence and position in Canada. A stronger life sciences sector would meet Canada's domestic needs, drive R&D, and improve the health and well being of Canadians.
2. A suspension of the July 1st, 2021 scheduled implementation of changes to the PMPRB is needed to allow all parties to address the COVID-19 pandemic and to provide more time to discuss alternative PMPRB changes that will still meet government's policy objectives but not impact the timely launch of new medicines in Canada. The imposition of flawed and controversial policy changes during a national health crisis is inappropriate and unreasonable given the need for governments, industry, and other stakeholders to prioritize resources to address COVID-19.



Key Considerations

- A reset of the federal government’s relationship and policy with regard to the innovative pharmaceutical industry is needed. Only through improved partnership can we build Canadian resiliency to effectively address current and future health crises.
- There is a clear need for long-term strategic thinking with respect to pharmaceutical and vaccine innovation and supporting domestic life-sciences R&D. A Canadian strategy can address domestic manufacturing, a more streamlined regulatory system, affordability, access for patients to drugs for rare diseases, and incentives for investment.
- Canada has a history of a strong and vibrant life-sciences sector. However, years of public policy decisions by governments of all stripes have made Canada less attractive to industry investment and commercial activity. This includes measures like the PMPRB’s flawed regulatory changes which are scheduled to come into effect on July 1, 2021 and are causing companies to re-assess their capacity to invest in Canada. Other government policies, such as slow and burdensome drug listing processes, mediocre intellectual property protection, and layers of duplicative regulatory red tape, are similarly unhelpful. As a result, industry is increasingly investing in other jurisdictions, some of which are also outperforming Canada when it comes to vaccine acquisition. Our industry stands ready to collaborate with Canadian governments to improve the policy environment and build future domestic life sciences capacity.
- In addressing the COVID-19 pandemic, and throughout the multi-year PMPRB reform process, the innovative pharmaceutical and vaccine industry’s primary goal is to support the health and well-being of Canadians.
- Unfortunately, the PMPRB changes will do nothing to help achieve this objective and unless fundamentally altered, will limit access to new medicines and vaccines in Canada.¹
- The proposed changes to the PMPRB reflect a multi-year policy failure, given that no savings have been realized since the changes were first announced in 2016. Additionally, a critical component of the new regime has been invalidated by the Federal Court of Canada, yet the PMPRB continues to push forward with Guidelines changes that are not ready to be implemented in a few short months.

¹ *The PMPRB has essentially acknowledged that the proposed regime will have negative access consequences by creating exemptions from the Guidelines for COVID-19 medicines and vaccines. Why is this special treatment needed for some products, but no similar measures provided for other Canadian patients who will be negatively impacted, such as those suffering from cancer, cystic fibrosis, and a range of other severe illnesses? Regardless of PMPRB policy declarations, the industry and patients do not have ultimate assurances that PMPRB changes will not impact COVID-19 patented products, because these exemptions are non-binding and subject to change by the PMPRB at any time.*



- Innovative medicines manufacturers have put multiple alternative solutions on the table to address affordability objectives in a manner that would preserve timely patient access in the future. To date, repeated attempts by the industry to work collaboratively on a more pragmatic path forward have been rejected by Health Canada.
- Third party analysis suggest that Canadians will realize \$19.8 billion in savings over ten years on international basket changes alone (i.e., through price comparisons with other countries). This significantly exceeds Health Canada’s outdated estimate of \$13.2 billion in savings.
- The industry has also offered an additional \$1 billion to help address rare diseases and a made-in-Canada manufacturing and commercialization accelerator. These proposals were not final offers, but rather, a starting point for a conversation on some of the key issues like domestic manufacturing that we must address, together, moving forward.
- However, Health Canada has not engaged in meaningful dialogue on these alternatives and has consistently ignored concerns of many stakeholders, including patients, the rare disease community, life sciences groups, provinces including Quebec and Ontario, and producers of innovative medicines and vaccines.
- We are calling on others within the federal government to show leadership on behalf of all Canadians to improve and re-build the life-sciences sector in Canada. It starts with a recognition of industry’s value to Canada, a commitment to improving the relationship between industry and government, and a fundamental rethink of changes to the PMPRB.