



Innovative Medicines Canada

2022 Federal Pre-Budget Consultation

August 6, 2021

About Innovative Medicines Canada

Innovative Medicines Canada (IMC) is the national association of 47 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 many of the vaccines, medicines, and diagnostics that are enabling Canada to emerge from the global pandemic that continues to have a devastating impact on the health and prosperity of Canadians.

Recommendation 1 – Implementation of an Effective National Strategy to Enhance the Canadian Pharmaceutical and Vaccines Industry

- 1. The innovative medicines and vaccines industry calls on the federal government to implement concrete measures under the recently announced national [Biomanufacturing and Life Sciences Strategy](#)¹ to build a more vibrant life sciences sector and enhance patients' access to innovative new medicines. Consistent with the strategy's Pillar 5: "Enabling Innovation by Ensuring World Class Regulation," the government should urgently suspend the amendments to the PMPRB's regulations which would undermine the government's more progressive life sciences objectives. The strategy must address critical issues like manufacturing, a more streamlined and predictable regulatory system, affordability, patient access to drugs for rare diseases², promoting innovation including medicines to address antimicrobial resistance, and incentives for investment.***

The COVID-19 pandemic has highlighted that the innovative pharmaceutical and vaccine industry is critical to Canadians' health. A stronger life sciences sector would help to meet Canada's domestic needs, drive R&D, and improve the health and well being of Canadians. Only through improved partnerships can we build Canadian resiliency to effectively address current and future health crises.

Canada has a vibrant life-sciences sector, but years of public policy decisions by governments of all stripes have gradually made Canada less attractive to industry investment and commercial activity. The most recent example is the flawed and controversial regulatory reform to the Patented Medicine Prices Review Board (PMPRB), which is scheduled to come into effect on January 1, 2022. These changes are opposed by the industry, patient groups and life sciences organizations, and are in direct opposition to the government's

¹ Innovation, Science and Economic Development Canada (ISED) July 2021 [Biomanufacturing and Life Sciences Strategy](#)

² See [IMC Submission](#) to Health Canada's March 2021 consultation on Drugs for Rare Diseases.



Life Science Strategy objective to enable innovation by ensuring world class regulation. 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.

Canada can learn from jurisdictions such as the UK that have recently advanced life science strategies which include intellectual property incentives,³ and investments in early patient access to breakthrough technologies including drugs for rare diseases (see UK Innovative Medicines Fund).⁴ In contrast, the uncertainty caused by the current Canadian policy and regulatory environment risks jeopardizing access to new medicines, including access to drugs for rare diseases and medicines to address antimicrobial resistance.

Our industry stands ready to collaborate with Canadian governments to improve the policy environment and build national pharmaceutical and vaccine capacity. There is a clear need for long-term strategic thinking with respect to pharmaceutical and vaccine innovation and supporting domestic life-sciences R&D. Because no strategy can be successful without fundamentally rethinking the changes to the PMPRB, we are encouraged by the inclusion of both ISED and Health Canada as part of the Life Sciences Strategy. Replacing the PMPRB changes with a more predictable pricing regime would send a clear signal internationally that Canada will advance its aspirations for life sciences leadership with meaningful action.

Recommendation 2 – Suspend and Fundamentally Rethink PMPRB Regulatory and Guidelines Changes

- 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 insist that the PMPRB discontinue concerning new policy proposals⁵ released in July 2021 that undermine regulatory delays intended to account for the COVID-19 pandemic. The government should suspend the implementation of the PMPRB regulatory and guidelines changes until the COVID-19 pandemic has abated.***

A suspension of the scheduled implementation of the PMPRB changes is needed to allow all parties to address the COVID-19 pandemic and to provide more time to discuss alternatives to the PMPRB changes that will still meet the government's policy objectives without negatively impacting the launch of new

³ UK's recently published [Life Sciences Vision paper](#) highlights greater protections for IP (i.e. "Over the next decade, the UK will unequivocally champion open, competitive free trade and work to support the Life Sciences sector, through tariff elimination, a strong rules-based approach to tackling non-tariff barriers, promoting IP regimes that are more closely aligned with the UK's gold standard globally and through creating the most hospitable environment possible for inward investment" (p. 42)).

⁴ See [UK Innovative Medicines Fund](#). See also [UK Rare Disease Framework](#).

⁵ PMPRB July 2021 [Notice and Comment](#).



medicines and vaccines in Canada. Innovative medicine and vaccine manufacturers have proposed several alternative solutions to address affordability objectives in a manner that would preserve timely patient access in the future. To account for the COVID-19 pandemic, the government has provided a regulatory delay to January 1, 2022 which should be used for further meaningful discussion of potential alternatives.⁶

Unfortunately, this delay has caused the PMPRB to take matters into its own hands by proposing new punitive and retroactive policy changes to its pricing tests without a compelling rationale for changing its guidelines yet again.⁷ These changes will accelerate the negative impact to innovators at a sensitive time during the pandemic and, by PMPRB's own admission, will have a more significant economic impact than its last proposal. PMPRB must discontinue this proposal and honour its previous commitment to a 12-month transition period from the effective date of regulatory amendments, which is needed given the magnitude of the changes envisioned and the ongoing pandemic.

In conclusion, the imposition of flawed and controversial policy changes during a national health crisis is counterproductive and unreasonable given the need for governments, industry, and other stakeholders to prioritize resources to address COVID-19. We are calling upon the federal government and other stakeholders to show leadership on behalf of all Canadians to improve and enhance the life-sciences sector in Canada. A starting point would be a recognition of the industry's value to Canada, a commitment to improving the relationship between industry and government, and a fundamental rethink of the PMPRB's regulatory and guidelines changes.

⁶ "If the industry has alternatives to the proposed [PMPRB] changes that result in that same goal, which is accessible, affordable medication, [then] of course, as the minister of health, I'm always interested in hearing those ideas"- Minister of Health, Patty Hajdu, June 29, 2021

⁷ PMPRB July 2021 [Notice and Comment](#).