



Innovative Medicines Canada

ISED Consultation on Biomanufacturing

March 12, 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. According to Statistics Canada, in 2018 the sector added almost \$15 billion in value added (GDP) to the Canadian economy and supported over 100,000 full-time equivalent jobs within Canada. Additionally, it invested nearly \$2.0 billion on research and development. These investments are a critical component of our industry's contribution to Canada's innovation ecosystem.

Recommendations

- 1. The innovative 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 new medicines and vaccines. 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. The federal government should recognize the critical role that the innovative biologics and vaccines industry can play in meeting Canada's aspirations regarding future domestic life science capacity and resilience. Our industry is one of the few in Canada with biomanufacturing expertise and therefore meaningful partnership is critical. For any future investments or joint initiatives, the government should carefully consider the appropriateness of arms-length governance and benefits of private enterprise.*
- 3. Market-based solutions can be leveraged to help Canada avoid creating ineffective or inefficient "white elephant" institutions. As such, any future commercially focused projects should involve a competitive tendering and an arms-length feasibility assessment. A market-based approach can help Canada better integrate into North American and global supply chains.*
- 4. An attractive commercial and regulatory environment is one of the most important elements for building robust life science capacity and system resilience. A holistic perspective regarding the commercial environment for life sciences is needed, which includes but is not limited to biomanufacturing. 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 new innovative medicines. A fundamental reconsideration of the PMPRB changes is required. At a minimum, the government should delay the implementation of PMPRB regulatory changes until the COVID-19 pandemic has fully abated.*
- 5. Our industry stands ready to collaborate with governments on a pan-Canadian pandemic preparedness function as well as targeted improvements to the regulatory and policy environment to accelerate Canada's biomanufacturing capacity, improve timely access, and help innovations scale up domestically.*



Rationale

The Covid-19 pandemic has highlighted that the biopharmaceutical and vaccines industry is critical to Canadians' health and well being yet its relationship with government needs a constructive 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. This can be accomplished by focusing on improvements to the regulatory environment and targeted partnerships.

An uncertain and unfavourable policy and regulatory environment continues to be major obstacle to growth and investment. Specifically, the proposed PMPRB regulatory changes continue to be the serious obstacle to growing a life science capacity in Canada. 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 the federal 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.

Context

IMC is encouraged to see the federal government commit to building Canada's domestic life sciences sector and manufacturing capacity. COVID-19 has reinforced how important the pharmaceutical and vaccines sector is to Canadians' health and well-being, and to our economy. Our industry has an important role to play and the public-private partnership dimension of the government's discussion paper is an important step in that direction. We look forward to contributing meaningfully to the dialogue.

Given that IMC approached the federal government in Fall 2020 with a proposal to jointly establish a biomanufacturing accelerator with significant private investments, we question the accelerated time frame of just three weeks for the current consultation. This seems *pro forma* and does not allow stakeholders sufficient time to fully consider the wide-ranging consultation document. As such, we do not answer all of Innovation, Science and Economic Development Canada's (ISED) detailed consultation document questions herein, but rather addressed them during ISED's March 12th consultation session. Instead, we will focus on a few key themes and recommendations.

Our central recommendation is that the government focus its immediate efforts on 1) improving the commercial and regulatory environment; 2) working collaboratively to establish a pan-Canadian pandemic preparedness function; and 3) take sufficient time and fully consult when developing other more aspirational and commercially focused mechanisms to ensure carefully crafted policies and prudent investments with appropriate governance. Because Canada's vaccine needs for the COVID-19 pandemic are addressed through many existing contracts with the international industry, and building capacity at scale cannot happen overnight, the key opportunity is to build capacity and resilience for the future. Canada should strive to become a more important part of the global supply chain and not create policy in isolation.



Biomanufacturing investments are global decisions. Other nations are currently engaged in the same exercise regarding building their life sciences footprints in a competitive global context, and Canada needs something to stand out among many competing nations and build a unique role and value contribution within the broader global supply chain. For example, Canada's proximity to the U.S. market and major life science players is a major asset and provides several opportunities for Canada to integrate within U.S. and European supply chains.

Our industry is proud of our role to help Canada and the world emerge from the Global COVID-19 pandemic. We have also made significant industry investments in more micro-level initiatives such as the establishment of a [research chair in pandemic preparedness](#) in May 2020. We therefore support larger scale initiatives in this area such as the idea of a pan-Canadian centre for pandemic preparedness that includes strong collaboration with provinces and the private sector, given their respective roles in health care delivery and the production of innovative medicines and vaccines.

Reflecting on the past to inform a productive path forward

An attractive regulatory environment is perhaps the most important element of building robust life science capacity and resilience. 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. While the PMPRB regulatory changes are the most recent and prominent example, other government policies, such as slow and burdensome drug listing processes, including significant delays at the Pan-Canadian Pharmaceutical Alliance's negotiation processes, mediocre intellectual property protection, and layers of duplicative regulatory red tape, are similarly unhelpful. We recommend that Canada review and re-focus the mandates and performance metrics of regulatory, pricing, health technology assessment and listing/reimbursement agencies in Canada to help make us a leader in the adoption of health technologies.

From an international perspective, Canada seems by turn either reluctant or indifferent to intellectual property protection for life sciences innovators. For example, the Spring 2020 COVID-19 related amendments to the *Patent Act* were made with no notice to, or consultation with, the industry most impacted by the amendments.¹ While ultimately time-limited and unused, these amendments generated international attention and sent the wrong signal at the wrong time with respect to Canada's perspective on protecting innovation. Similarly, Canada must stand with innovators in rejecting patent waivers as a solution to build vaccine capacity, given there is no credible evidence supporting such a waiver². Canada can also take a more active role in championing innovation in trade agreements and international organizations such as

¹ *COVID-19 Emergency Response Act*, S.C. 2020, c. 5, Part 12.

² See: <https://writtendescription.blogspot.com/2021/03/are-patents-cause-of-for-solution-to-covid.html>



the World Trade Organization and World Health Organization. In doing so, Canada would send a strong signal internationally that it is intent becoming a life sciences leader.

In addressing the COVID-19 pandemic, and throughout the multi-year PMPRB regulatory change process, the innovative pharmaceutical and vaccine industry's primary goal has been to support the health and well-being of Canadians. Unfortunately, the PMPRB changes will not help to achieve this objective and unless fundamentally altered, will limit access to new medicines and vaccines in Canada.³ 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. The industry has also offered an additional \$1 billion to help address rare diseases and a made-in-Canada biomanufacturing 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.⁴

Given that repeated attempts by the industry to work collaboratively on a more pragmatic path forward have been rejected, a reset of the federal government's relationship and policy with regard to the innovative pharmaceutical industry is needed to form a new and lasting partnership.

These consultations open the door to a new approach, and better, more productive relationship in which ISED can play a leadership role in championing a more vibrant future for the sector. A stronger life sciences sector, with industry as a key pillar, would meet the country's domestic needs, drive R&D, and enhance the health and well-being of Canadians.

Market-based solutions and appropriate governance

Market-based solutions can be leveraged to help Canada creating effective and efficient policy approaches and help the government build a self-sustaining domestic capacity that is driven by commercial realities and economic principles. The federal government's primary role as the national health and safety regulator means that it must rely on private industry to continue to be the primary producer and marketer of regulated health products. Our industry and other life sciences sector members (e.g., medical devices, generics and

³ 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.

⁴ 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 Québec and Ontario, and producers of innovative medicines and vaccines.



CDMOs) have considerable experience in commercializing innovations and stand ready assist the government with its aspirations to help Canadian innovations scale up domestically.

A commitment to market-based policies such as the free movement of goods, opposition to supply chain restrictions, improved IP protection, reduction of red-tape, and other commercial environment considerations will go a long way to help Canada build confidence and attract investment partners.

Policies that incentivize, rather than mandate, increased local production can strengthen domestic manufacturing supply chains, generate jobs, and reduce costs, while also supporting innovation. Global supply chain benefits can be maximized when policymakers reject export bans and trade restrictions, therefore building more resilient supply chains. For instance, the WTO Ottawa Group that also includes Canada, rightly recognizes that responses to new and emerging health crises have an important international dimension that requires increased cooperation among trusted trade partners to avoid unnecessary disruption.

Market-based investment solutions, for example those that reflect commercial viability and sustainability, can also be leveraged to help Canada avoid creating ineffective or inefficient institutions. For any future investments or joint initiatives, the government should carefully consider the appropriateness of arms-length governance and benefits of private enterprise. As such, any future commercially focused projects should involve clear project objectives, competitive tendering to meet these goals, and an arms-length feasibility assessment. A key criterion could be projects which help Canada more closely integrate into North American and global supply chains, leveraging Canada's comparative advantages and highly educated workforce.

In summary, IMC believes that a productive path for Canada involves **establishing a new and lasting partnership; supporting the uptake and adoption of innovation; implementing agile, efficient, and predictable regulatory systems; and enhancing Canada's international attractiveness**. This will require a sustained and multi-year effort by governments, industry, and other stakeholders but can produce health and economic benefits to Canada for decades to come. There is a clear need for long-term strategic thinking with respect to biopharmaceutical 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. In the coming weeks, we will again reach out to the Ministers of Innovation, Health, Procurement and Finance to engage in such discussions. We look forward to the opportunity to discuss next steps in greater detail.