WRITTEN SUBMISSION FOR THE PRE-BUDGET CONSULTATIONS IN ADVANCE OF THE UPCOMING 2021 FEDERAL BUDGET

By: Innovative Medicines Canada

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RECOMMENDATIONS

- **Recommendation 1:**
  That the government strike a balance between affordability and access to innovative medicines and vaccines. Balance can be achieved by suspending changes to the Patented Medicine Prices Review Board (PMPRB) and working together to ensure affordable treatments and vaccines are rapidly available to Canadians.

- **Recommendation 2:**
  That the Federal government provides additional funding and research incentives over the next 5 years to its AMR One Health Network and work with the Canadian Antimicrobial Innovation Coalition (CAIC) to address the growing public health threat of antimicrobial resistance (AMR).

- **Recommendation 3:**
  That the government work in cooperation with the provinces, territories, life sciences organizations and the pharmaceutical industry to develop a National Life Sciences Strategy (NLSS) for Canada and implement it over the next 10 years with appropriate funding.

Innovative Medicines Canada (IMC) is the national voice of Canada's innovative pharmaceutical and vaccine industry. We are committed to working with all governments to ensure Canadian patients have access to the best innovative medicines and vaccines in the world, and for contributing to the long-term sustainability of Canada's health care systems. We are pleased to provide the Committee with three positive contributions intended to support the federal government's objectives related to a green economic recovery.

- **Recommendation 1: That the government strike a balance between affordability and access to innovative medicines and vaccines. Balance can be achieved by suspending changes to the Patented Medicine Prices Review Board (PMPRB) and working together to ensure affordable treatments and vaccines are rapidly available to Canadians.**

The global outbreak of the novel coronavirus (COVID-19) has shone a light on the importance of the critical investments required to create and strengthen models for innovation within Canada's pharmaceutical ecosystem. Pharmaceutical innovation plays a critical role in increasing the sustainability of the health care system by creating vaccines – one of the most cost-effective public health interventions, and thereby decreasing medical visits and hospitalizations.

This primary recommendation does not require a specific Budget 2021 expenditure, but would have a positive and stabilizing effect on our industry at a critical time. In order to allow both industry and government to focus on addressing the COVID-19 pandemic, the Finance Minister should work with his Cabinet colleagues to suspend regulatory changes to the Patented Medicine Prices Review Board (PMPRB). This can be accomplished through a stroke of the pen (i.e. an Order-in-Council to remove pending regulatory changes which were made on August 21, 2019, before the onset of the pandemic).

Suspending these detrimental regulations would enable the pharmaceutical and vaccine industry to avoid significant job loss and reductions in Canadian clinical trials.

Our member companies contribute $19.2 billion annually to the national economy and directly and indirectly support 30,000 high-quality jobs across Canada. Those Canadians are working hard to help address the COVID-19 pandemic and other diseases, and are hoping to have a partner in government that understands businesses need predictable regulations.

Industry recognizes it must also do its part to help the Government achieve its policy objectives regarding affordability, investment in R&D/innovation, protecting the under-/uninsured, and strengthening the supply chain/domestic production. To benefit Canadians who suffer from severe diseases each day and to ensure the sustainability and improvement of our health care systems, we need a collaborative approach that will allow us to quickly get price reforms right for Canadians without risking access to medications or investment.

- **Recommendation 2: That the Federal government provides additional funding and research incentives over the next 5 years to its AMR One Health Network and work with the Canadian Antimicrobial Innovation Coalition (CAIC) to address the growing public health threat of antimicrobial resistance (AMR).**

Antibiotic resistance and superbugs are one of the biggest public health challenges of our time. Researchers at the University of Toronto (UT) and Boston Children's Hospital also link the emergence of drug-resistant bacteria to a hotter climate.[1] It is expected that the world will experience a rise in the appearance of superbugs and by 2050, infections resistant to antibiotics will be the leading cause of death worldwide. "With the interconnected ecosystems of humans, animals and the environment, the exchange of bacteria is continuous. The role of the environment, particularly water, in the spread of antibiotic-resistant bacteria is increasingly gaining attention.[2]

In Canada, 26% of infections are resistant to the drugs that are generally used to treat them.[3] It is estimated that by 2050, a total of 256,000 lives could be lost in Canada, and could reduce Canada's annual GDP by $268 billion.[4] A panel of experts found that in 2018, AMR cost $1.4 billion and reduced Canada's GDP by an estimated $2 billion. This burden will continue to increase.[5]

Since 2010, 15 new antibiotics approved by the U.S. Food and Drug Agency (FDA) were approved, but none were launched in Canada. Some companies have mentioned that their decision not to launch or seek approval for their antibiotics in Canada was related to the new PMPRB pricing regime.

The Prime Minister prioritized antimicrobial resistance in the Minister of Health's Mandate Letter by including the development and implementation of required actions with partners to preserve the effectiveness of the antimicrobials. IMC strongly believes that this work should be conducted in cooperation with partners from the pharmaceutical industry, key health care stakeholders, and international governments. Canadians will benefit from working collaboratively on these hazardous microbial by sharing knowledge, research development as well as cost-sharing partnerships which will provide greater incentives and successes.

AMR has been a priority for the international pharmaceutical industry and the World Health Organization (WHO) for many years. IMC's global members have also been working to address this issue in a constructive and collaborative way. For example, in July 2020, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) announced a $1 billion AMR Action fund raised by more than 20 leading biopharmaceutical companies. As the website states: "the concept of the AMR Action Fund has been developed in collaboration with the WHO, the European Investment Bank, and the Welcome Trust. It aims to overcome key technical and funding barriers of late-stage antibiotic development and will work with

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[1] *https://www.nature.com/articles/s41558-018-0161-6*
[2] *https://indiaclimatedialogue.net/2018/01/05/climate-change-amplifies-superbugs-resistance-antibiotics/*
[3] *https://cca-reports.ca/forecasting-the-future-of-amr/*
[4] *Ibid.*
[5] https://cca-reports.ca/reports/the-potential-socio-economic-impacts-of-antimicrobial-resistance-in-canada/

governments to ensure there is a sustainable pipeline of new antibiotics to fight superbugs. This groundbreaking partnership aims to bring 2-4 new antibiotics to market this decade that will save patient lives."

Building on global partnerships and knowledge of our members, Canadians would benefit from a cooperative and a financial risk-sharing approach. As we have seen since the beginning of the current pandemic, collaboration provides better and faster outcomes.

- **Recommendation 3: That the government work in cooperation with the provinces, territories, life sciences organizations and the pharmaceutical industry to develop a National Life Sciences Strategy (NLSS) for Canada and implement it over the next 10 years with appropriate funding.**

While each province is developing, or implementing in the case of Québec, its respective life sciences strategies according to their provincial economies, the federal government could play an important role in coordinating and supporting those efforts. By working with the pharmaceutical industry and each province to develop incentives, the federal government can help market Canada as an attractive place to invest in this vital sector.

This NLSS should support strategic pillars of the provinces and territories' respective life sciences (LS) strategies and should be tailored to help grow Canada's international reputation as a key LS innovators hub. As previously mentioned, COVID-19 has demonstrated the importance of having a strong LS ecosystem in our country to help us emerge from health crises, but also to ensure that our health care systems stay stable, sustainable and provides the best care possible for Canadians. Building on recent lessons learned, it is important to continue working together to promote Canada's LS sector.

A Canadian life sciences strategy could produce a dual benefit of both economic development and health system sustainability through innovation. It could build on the HBEST recommendations to ensure patients have better outcomes and Canada's life sciences eco-system flourishes with scale. The strategy could ensure industry and governments are aligned as innovation enablers to maximize Canada's research talent, data and infrastructure. It could position Canada as a preferred destination for clinical trials.

The development of a "made-in-Canada" collaborative innovation framework for drugs for rare diseases has been a long-standing public policy objective for governments, patients, and our industry. We encourage the government to support the needs of patients with rare diseases by deploying and building upon the $1 billion dollars announced in Budget 2019 which could be appropriately used for innovative evaluation and procurement solutions to directly benefit patients with rare diseases. Innovative pharmaceutical companies have been working with governments and patients around the world to develop and implement solutions that are helping patients with rare diseases. Recent examples where there has been success include Scotland's new program that provides earlier access for patients to new medicines for a three-year period while gathering information on their effectiveness; and Australia's Life Saving Drugs Program, which provides fully subsidized access to essential medicines to eligible patients with rare and life-threatening diseases. Through their global experience, our member companies have a sense of what approaches and solutions have worked in other countries, and how these learnings could be applied in Canada.

A national Real-World Evidence (RWE) database should be an integral part of the framework and a key tool in a NLSS for Canada. Such a database in the innovative pharmaceutical world would be incredibly important to improve patient outcomes, cut costs and reduce time to market. Rigorous and uniform data collection

protocols are important, and the federal government is well positioned to play a coordinator role and host this database.

The Federal government is well positioned to expand its newly formed CAN Health Network and bridge a whole-of-government approach to develop a comprehensive and integrated NLSS and explore strategic opportunities favouring partnerships with industry.

Building on priorities outlined in provincial LS objectives, the federal government can financially and structurally support provinces and territories in the implementation of their respective LS strategies by also leveraging their priorities. Integrating the objectives of the HBEST report and bringing all government departments together towards these same objectives will help move this important economic policy forward.

Conclusion

As previously explained, these meaningful policy objectives are at risk given the PMPRB's new regime, which will undermine our industry's capacity to continue investing and to maintain current levels of clinical trial activity in our country. The PMPRB regulations will have particularly severe impacts for many new rare disease medicines and may impact their availability in Canada, which will make a rare disease framework ineffective.

To compete on a global scale, Canada must have regulatory frameworks that attract local and international capital investment and the required talent to compete with similar economies, all while ensuring that patients have access to innovative medicines.

On the road to economic recovery and health care sustainability post COVID-19, the innovative pharmaceutical industry can play an active role in helping Canadians emerge from the pandemic. Working together, we can achieve a stable innovative life sciences environment that provides better health, access to new medicines, economic opportunities, and enhanced protection and preparedness in the wake of the global pandemic.