INNOVATIVE MEDICINES CANADA

INCREASING ACCESS TO INNOVATIVE MEDICINES

Written Submission for the Pre-Budget Consultations in Advance of the Upcoming Federal Budget.

AUGUST 2, 2024

RECOMMENDATION 1

NATIONAL PHARMACARE: Encourage thorough consultations and substantive review of key stakeholder perspectives during the Senate study of Bill C-64, An Act Respecting Pharmacare, greater precision regarding the objectives, scope, details, and financial implications of the legislation.

- The federal government should consult with a broader group of stakeholders and clarify its intentions for national pharmacare and should ensure that the legislation provides funding and other support to help fill the existing coverage gaps within provincial and territorial drug plans.
- The federal government should spell out within the legislation the commitment to ensuring a broad variety of stakeholders, including industry, be part of the composition of the committee of experts.
- The federal government should ensure that the legislation does not reduce or delay access to new medicines and therapies for those with employer-sponsored drug benefits.

RECOMMENDATION 2

REGULATORY AND POLICY ENVIRONMENT FOR ACCELERATED ACCESS TO MEDICINES: Improve regulatory and policy environment to encourage timely access to new medicines in order to promote innovation within Canada and enable the sector to contribute to driving the economy.

- Continue to work with the provinces to complete and secure the bilateral agreements as part of the Drugs for Rare Diseases Strategy so that patients can benefit from greater access to treatment options, screening, and diagnostic capacity.
- Continue to work with the provinces to support their jurisdictional responsibilities for the delivery and implementation of healthcare programs and services which aim to improve the health of Canadians and prevent disease.
- Enact more ambitious Agile Licensing Regulations and better align with international peer jurisdictions.
- Reduce the 5-month time gap from HTA to pCPA uptake.
- Ensure that the Patented Medicine Prices Review Board (PMPRB) works collaboratively with industry and other stakeholders to finalize predictable guidelines which are consistent with its excessive pricing mandate.
- Commit to clear actions on antimicrobial resistance by fully funding and launching a pull incentive pilot and implementing the commitments in the Pan-Canadian AMR Action Plan.

INTRODUCTION

Canada's healthcare system is in crisis, and Canadian patients deserve access to healthcare innovation[1] that delivers the total health that they expect. Innovative medicines play an essential role in keeping Canadians healthy and relieving pressure on healthcare systems. However, Canadians are waiting too long for the medicines they need, and sometimes they cannot access important new treatments. Only 18% of new medicines launched globally are available through Canada's public drug plans, while the OECD average is 28%. In addition, Canadians wait two years, on average, for access to new medicines through public drug plans following Health Canada approval. For rare disease drugs, the approval process can take up to six years longer than in the U.S. or Europe, according to the Canadian Organization for Rare Disorders.

Our industry contributes to the total health of Canada and, for decades, has driven healthcare innovation – we support over 100,000 high-value jobs, invest $2.4 billion in R&D[2], and contribute nearly $16 billion to the economy each year[3]. Collaboration with government to create policies and regulations that help position Canada as an attractive destination for future R&D and life sciences investments is critical. Canadian scientists and clinicians benefit from exposure to cutting-edge scientific development, and patients benefit from early access through clinical trials. This will help to ensure that Canada remains competitive with other jurisdictions within the global life sciences sector.

Innovative Medicines Canada (IMC) has developed this submission for the Standing Committee on Finance's consultations in advance of Budget 2025, presenting a path forward that places the focus on Canadian patients and getting them the life-saving medicines and vaccines they need as soon as possible. IMC looks forward to engaging meaningfully with government to find collaborative solutions that benefit all people living in Canada.

ISSUES

- Canada lags peer countries in the **number of new medicines available** and the **time it takes for patients to access medicines** for better health outcomes.
- Currently, there is policy uncertainty regarding the changes to the PMPRB's Guidelines and the federal government's approach to national pharmacare legislation Bill C-64, An Act Respecting Pharmacare, which lacks clarity.

[1] Healthcare innovation in this context refers to: innovative treatments which use the best available science and technology; seamless care pathways, including better screening and diagnostics; and the expanded use of health data and real-world evidence to improve healthcare decision-making at the individual, system, and population levels.

[2] The pharmaceutical and biotechnology industry has the second largest Canadian business expenditures in R&D (BERD) expenditures intensity in 2020: https://ised-isde.canada.ca/site/canadian-life-science-industries/en/biopharmaceuticalsand-pharmaceuticals/clinical-trials-environment-canada

[3] https://www150.statcan.gc.ca/n1/pub/11-621-m/11-621-m2023001-eng.htm

RECOMMENDATION 1

NATIONAL PHARMACARE: Encourage thorough consultations and substantive review of key stakeholder perspectives during the Senate study of Bill C-64, An Act Respecting Pharmacare, greater precision regarding the objectives, scope, details, and financial implications of the legislation.

All Canadians should have access to the medicines and vaccines they need, when they need them, regardless of income, age, or postal code. As the federal government considers its path forward on national pharmacare, IMC continues to urge the adoption of an approach that seeks to fill the current gaps in the dual-market public/private system, ensuring that uninsured and underinsured Canadians get access to the medicines they need, while protecting the value of private plans for the 24.6 million Canadians who are currently enrolled in one. This approach also allows provinces and territories to customize their programs to meet each jurisdiction's unique needs. Moreover, it is preferred by the majority of Canadians and was welcomed by the federal government as a success in the context of its 2020 agreement with Prince Edward Island. According to a May 2024 survey of 2000 randomly selected adult residents of Canada, the gap filling approach is favored over a universal model by 45% to 36%. Furthermore, the prospect of a gap filling approach to pharmacare raises less concern and skepticism than does a universal coverage model. For example, 65% worry about the cost to taxpayers when implementing a universal approach, but only 49% feel the same about implementing an approach that fills existing gaps in coverage.

Given the limited information on the purpose and scope of pharmacare legislation and lack of specificity contained within the legislation, this important public policy issue merits extensive stakeholder dialogue and consultation before legislation is passed.

The federal government should allow provinces to determine their needs for their respective citizens and provide funding and other support to help fill the existing coverage gaps within existing provincial and territorial drug plans. It currently takes on average two years for most new medications to be covered by provincial plans with budget constraints playing a significant role in this delay across many provinces.

Additionally, the medications identified by the federal government for initial inclusion in pharmacare largely consist of older treatments. If these medications become available on the government's public plan, employer-sponsored private plans would likely stop providing them, or simply stop providing any drug benefits. The federal government should ensure that the legislation does not encourage employers to limit coverage, leading to reduced patient access to new medicines and therapies.

Further information on IMC's position can be found within IMC's 2023 submission on National Pharmacare. Or in IMC's May 2024 submission to the Standing Committee of Health study of Bill C-64.

RECOMMENDATION 2

REGULATORY AND POLICY ENVIRONMENT: Improve the policy and regulatory environment to encourage timely access to new medicines, focusing on those elements that are within federal control. Create an environment which allows Canadians to access the medicines they need, when and how they need them, by increasing availability of innovative medicines and vaccines.

The discovery, development and delivery of transformative medicines and vaccines help Canadians live longer and healthier lives.

At present, only 18% of new medicines launched globally are available to Canadians on public plans.

A whole-of-government approach is needed to connect several federal initiatives that impact medicine availability and the time it takes to get them to patients. While the federal government has limited tools when it comes to provincial and territorial pharmaceutical programs, it can make investments to support their efforts to improve availability and time-to-patient for new medicines.

IMC welcomed the March 2023 announcement of a National Strategy for Drugs for Rare Diseases (DRDs) which included up to $1.5 billion over three years to support the implementation of the strategy. We also welcome the recent federal agreement with British Columbia regarding funding for DRDs and hope that DRD agreements will be reached with the other provinces without delay. DRD patients need and deserve better access to new and emerging drugs and support enhanced access to existing drugs, early diagnosis, and screening for rare diseases. Additionally, as the implementation of the strategy moves forward, IMC believes that a standard definition for what constitutes a "rare disease" in line with international peers and Quebec should be adopted. In addition, a dedicated review, approval, and access pathway, centers of expertise, and the use of real-world evidence to more efficiently evaluate and approve DRDs would all help to increase access to important new treatments for Canadian patients.

Regarding advances to agile licensing regulations in 2023, IMC was pleased with the proposed amendments to the Food and Drugs Regulations. While the proposed amendments are necessary, the federal government needs to be more ambitious given the new technologies that are changing health systems globally, including innovations that will be developed through the use of Artificial Intelligence in research, the development of digital health solutions, and advancements in diagnostic testing.

Canada needs to keep pace with other jurisdictions through continuous improvement and forward thinking. As such, with increasing regulatory oversight and evolving international regulatory collaborations and convergence, IMC supports efforts to incorporate reliance frameworks, where appropriate, enabling Health Canada's ability to rely on peer regulatory agency reviews and approval of products to ensure that innovative medicines are available to Canadians in a similar timeframe to other parts of the world such as the United States, Europe or Japan. Canada must also continue to be at the forefront of regulatory innovation and agility, and IMC remains committed to supporting these efforts. Furthermore, IMC would welcome the federal government's work across jurisdictions to better align the work of the CDA with HTA to enact more congruent parallel processes.

Building on Health Canada's leadership at the regulatory level, other crucial steps in Canada's drug approval and reimbursement process should be streamlined to ensure the full societal benefits of faster access to new medicines are realized equitably for all Canadians. Of new medicines that are already available internationally, Canadian patients wait twice as long as patients in peer countries for public access to those medicines following Health Canada approval. Canada ranks last in the G7 and 19th out of 20 peer OECD countries in the time it takes for patients to get access to new medicines following regulatory approval. The federal government should work with other Canadian governments to improve the performance and capacity of the pan-Canadian Pharmaceutical Alliance (pCPA), including the introduction of new mechanisms and efficiencies to accelerate the negotiation process for new medicines.

In addition, the ongoing uncertainty associated with the PMPRB Guidelines remains a major source of concern for IMC members. The PMPRB should work collaboratively with IMC and other stakeholders to finalize predictable Guidelines that are consistent with its excessive pricing mandate.

CONCLUSION

IMC and its members are looking forward to building on our existing collaboration and partnership with the federal government. We continue to work productively with all levels of government and stakeholders across the country to ensure the sustainability of our healthcare systems and to get Canadians timely access to the innovative medicines and vaccines that they need.

ABOUT IMC

Innovative Medicines Canada represents Canada's innovative pharmaceutical industry. We help our members discover, develop, and deliver innovative medicines and vaccines, and contribute to the life sciences ecosystem across Canada. Guided by a strict Code of Ethical Practices, IMC members work with governments, private payers, healthcare professionals, and stakeholders to contribute to the total health of Canadians.

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