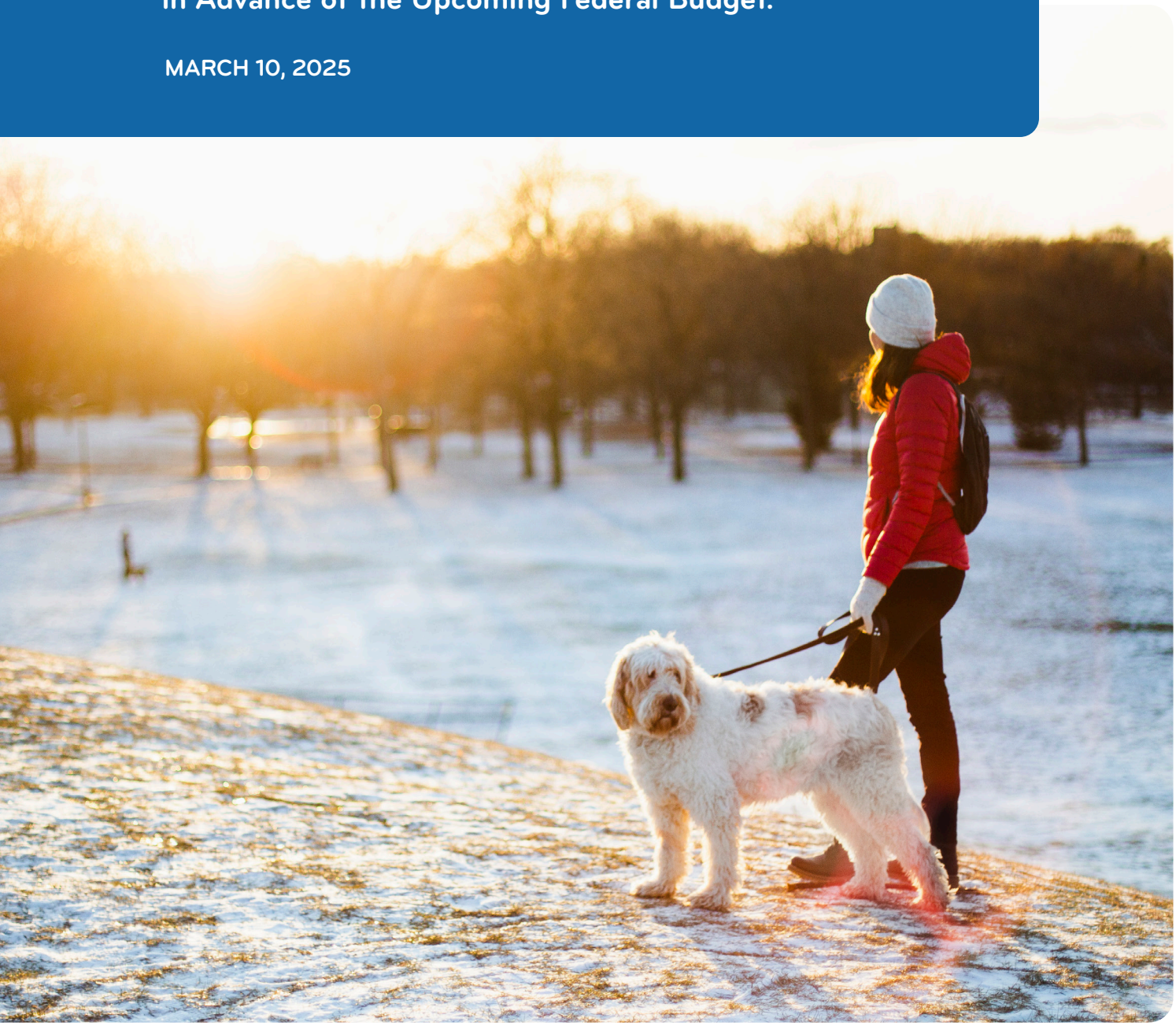
INNOVATIVE MEDICINES CANADA

INCREASING ACCESS TO INNOVATIVE MEDICINES

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

MARCH 10, 2025



RECOMMENDATION 1

ENHANCING CANADA'S REGULATORY AND POLICY FRAMEWORK FOR ACCELERATED ACCESS TO MEDICINES: Improving Canada's regulatory and policy environment is essential to ensuring patients have timely access to new medicines, foster innovation and enable the sector to strengthen the economy.

RECOMMENDATION 2

PROTECTING INTELLECTUAL PROPERTY IN CANADA: Protecting the intellectual property (IP) of pharmaceutical innovations that benefit Canadians.

RECOMMENDATION 3

ESTABLISH A LIFE SCIENCES WORKING TABLE: Collaborate with industry to create a quarterly working table on health and life sciences investments in research, and innovation.

INTRODUCTION

Canada's healthcare system is in crisis, and patients deserve access to healthcare innovation[1] that delivers the total health that they expect.

Innovative medicines and vaccines are amongst the most effective tools available to prevent illness, manage chronic disease, and, in some cases, provide life-changing cures. These innovations not only keep Canadians healthy, but they also help reduce strain on healthcare systems.

For example, since 2006, a vaccine has been available that can prevent up to 97% of cervical cancer cases caused by human papillomavirus (HPV). Beyond saving lives, these vaccines can generate up to $51.3M in annual savings to Canada's healthcare system by reducing the number of cases requiring treatment. They could also lead to $26.2M in indirect cost savings to the Canadian economy each year by preventing lost working hours due to illness[2]. Beyond cost savings, innovative tools and treatments mean Canadians can live longer, healthier and more productive lives.

However, Canadians are waiting too long for the medicines they need, and in some cases, they can't access them at all. Only 21%[3] of new medicines launched globally are available through Canada's public drug plans – well below the OECD average of 28%. On average, it takes two years after Health Canada approval for these drugs to become available through public drug plans. For rare disease treatments, the wait can be even longer — 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 more than 100,000 high-value jobs, invest $2.4 billion in R&D[4], and contribute nearly $16 billion to the economy each year[5].

Collaboration with government to create policies and regulations that attract R&D and life sciences investments is critical—especially as Canada faces growing uncertainty in its relationship with the U.S. Investing in the Canadian life sciences sector will help Canada stay competitive globally while giving Canadian scientists and clinicians access to cutting-edge research and provide patients with early access to innovative treatments through clinical trials.

Innovative Medicines Canada (IMC) has developed this submission for the Department of Finance's consultations in advance of Budget 2025, presenting a path forward that places the focus on faster access to life-saving medicines and vaccines for Canadian patients. We look forward to working with the government on collaborative solutions that benefit all Canadians.

ISSUES

- Canada trails peer countries in both the **availability of new medicines** and the **time patients wait for access to medicines**.
- Uncertainty around PMPRB's guideline changes and the ongoing U.S. trade dispute threatens Canada's economy and puts Canadian intellectual property at risk.

[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] 6456_IMC_ValueofMedicines_EFPIA_casestudies_2023_v5.pdf

[3] Global Access to New Medicines Report

[4] 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

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

RECOMMENDATION 1

REGULATORY AND POLICY ENVIRONMENT: Strengthen the federal policy and regulatory environment to ensure timely access to new medicines. In creating an environment that improves availability, Canadians get the innovative treatments they need, when they need them.

Breakthrough medicines and vaccines help Canadians live longer and healthier lives, yet only 21%of new medicines launched globally are available to Canadians through public drug plans.

A coordinated, whole-of-government approach is needed to streamline federal policies affecting medicine access. While provinces and territories manage their own pharmaceutical programs, federal investments can help strengthen the sector, improve availability of medicines and reduce wait times for patients.

IMC welcomed the March 2023 announcement of a National Strategy for Drugs for Rare Diseases (DRDs) backed by up to $1.5 billion over three years. With seven provinces already signing bilateral agreements, we urge the remaining provinces to finalize theirs without delay. Patients with rare diseases deserve better access to new and existing treatments, as well as improved screening and early diagnosis. As the strategy moves forward, IMC recommends adopting a standardized definition of "rare disease" aligned with international peers and Quebec. Establishing a dedicated rare diseases approval, review, and reimbursement pathway, along with leveraging real-world evidence, will help expedite access to life-changing new treatments for Canadians.

IMC also welcomed the 2023 proposed amendments to the Food and Drugs Regulations as a step forward for agile licensing. However, the federal government must be more ambitious to keep pace with global healthcare innovations, including AI-driven digital health solutions, gene and cell therapies and advancements in diagnostic testing.

To remain competitive, Canada should continuously improve its regulatory approach and align with international best practices. Health Canada should use the regulatory reliance frameworks / foreign decisions, where appropriate and as allowed under amendments to the Food and Drugs Act to support elements of "Precision Regulating," as passed in spring 2024.

IMC urges Health Canada to expand the reliance on foreign regulatory decisions beyond pediatric medicines, starting with post-NOC CMC changes and GMP inspections and testing, beyond those covered under Mutual Recognition Agreements and Memoranda of Understanding. This would ensure Canadians gain access to innovative medicines faster

Canada must also continue to be a leader in regulatory innovation and agility, and IMC is committed to supporting these efforts. We encourage the federal government to work across jurisdictions to better align Health Technology Assessment (HTA) and the Canadian Drug Agency (CDA), creating more streamlined, parallel processes.

Beyond regulatory improvements, Canada must also accelerate its drug approval and reimbursement pathways. Canadian patients wait twice as long as those in peer countries for public access to new medicines after Health Canada approval. Canada ranks last in the G7 and 19th out of 20 OECD countries in wait times following regulatory approval.

To improve access, the federal government should increase the accountability and transparency of organizations it funds to determine the economic value of new medicines (CDA) as well as those that negotiate drug prices (pCPA) to ensure negotiations are accelerated.

Additionally, ongoing uncertainty surrounding the PMPRB Guidelines remains a major concern for IMC members. The PMPRB should work closely with IMC and other stakeholders to finalize clear, predictable guidelines that align with its mandate on excessive pricing.

RECOMMENDATION 2

PROTECTING INTELLECTUAL PROPERTY IN CANADA: Protect intellectual property (IP) of pharmaceutical innovations that benefit Canadians.

As President Trump has threatened 25% blanket tariffs on all products imported from Canada, including medicines and treatments, the pharmaceutical supply chain is in an increasingly precarious state.

Canada's close integration in the North American supply chain means escalating trade disputes with the U.S. could threaten access to medicines. Tariffs on Canadian-made medicines, biologics, and vaccines and exported to the U.S. would be detrimental to Canadian and American patients, the Canadian life sciences ecosystem, and Canada's economic prosperity. Any actions, such as tariffs or other economic threats, that make Canada a less attractive destination for therapeutic launches or life sciences investment could have significant, lasting consequences for the entire healthcare system.

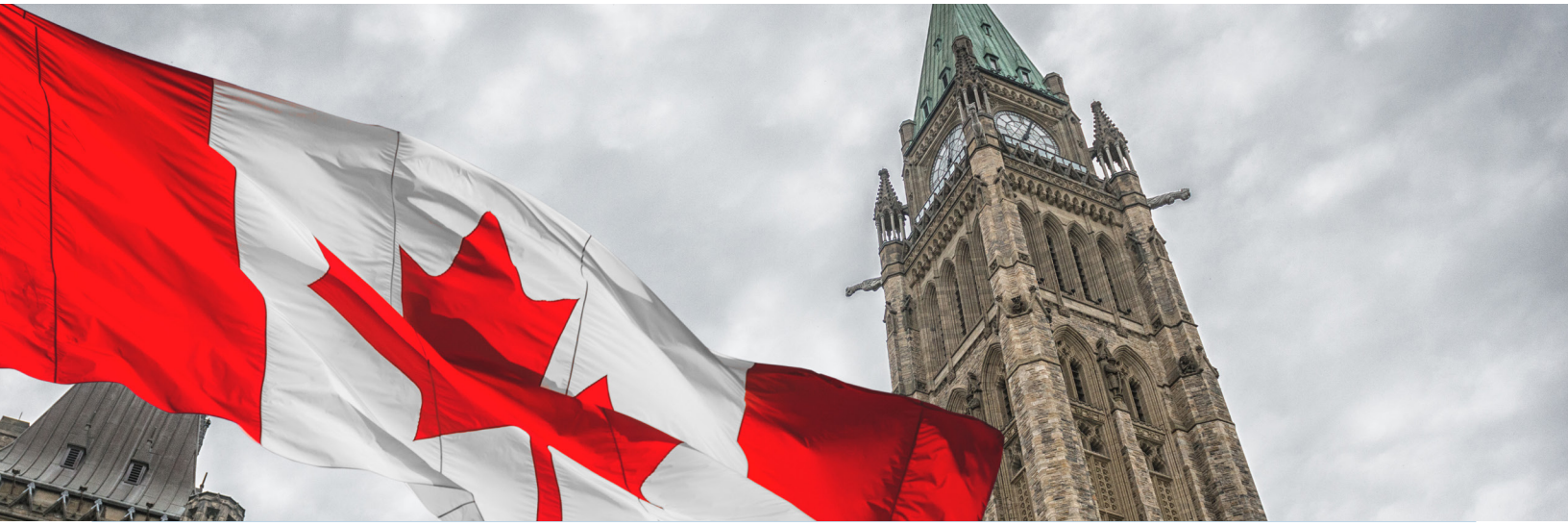
To safeguard access, all medicines, vaccines, manufacturing inputs, and materials necessary for packaging and shipping these pharmaceutical products should be protected from tariff and non-tariff retaliatory measures.

Additionally, strong intellectual property protections are essential to ensuring continued pharmaceutical innovations and better health outcomes for Canadians. Canada should take full advantage of the Patent Term Adjustment (PTA) framework under the Canada-U.S.-Mexico Agreement (CUSMA) to ensure patentees are compensated for patent term that is lost due to unreasonable delays in prosecuting a patent application.

RECOMMENDATION 3

ESTABLISH A LIFE SCIENCES WORKING TABLE: Collaborate with industry to create a quarterly working table on health and life sciences investments in research, and innovation.

This forum would bring together industry leaders and policymakers to address emerging challenges and explore ways the sector can support government health priorities. As the national association representing multinational innovative pharmaceutical companies in more than 120 countries, IMC is committed to working with government to develop policies that ensure Canadian patients get timely access to the medicines they need.

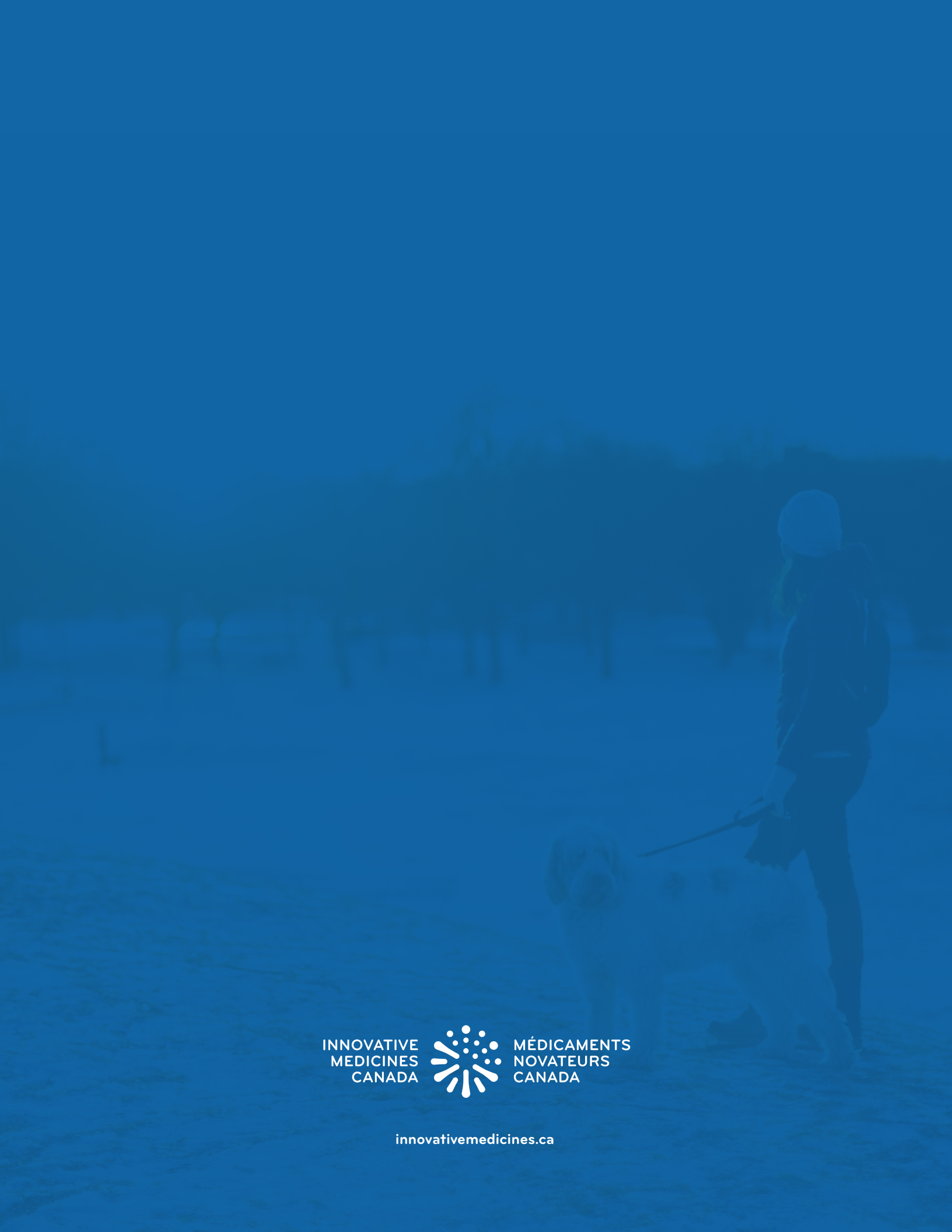


CONCLUSION

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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