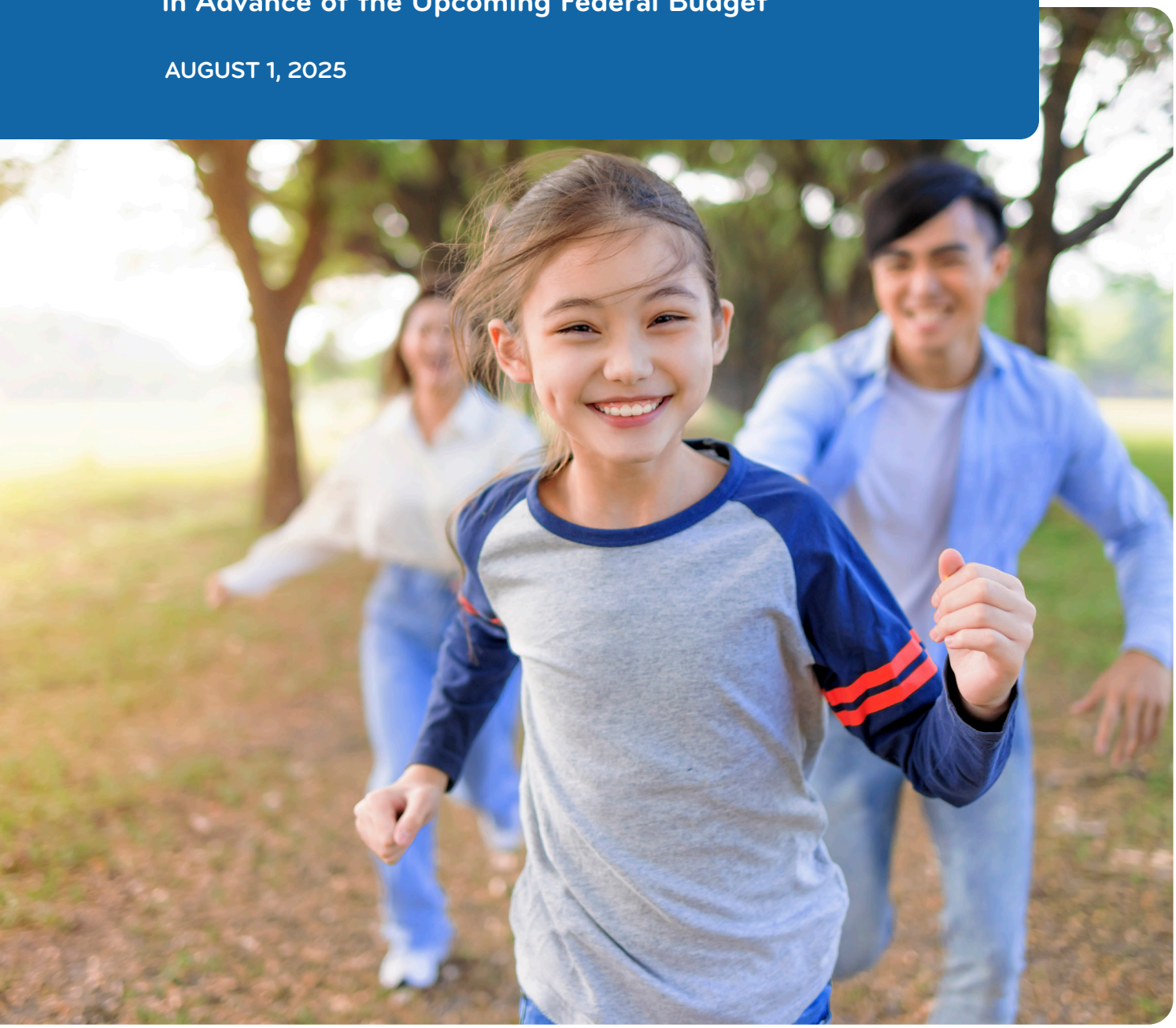
INNOVATIVE MEDICINES CANADA

# INCREASING ACCESS TO INNOVATIVE MEDICINES

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

AUGUST 1, 2025



RECOMMENDATION 1

**ENHANCING CANADA'S REGULATORY AND POLICY FRAMEWORK FOR ACCELERATED ACCESS TO MEDICINES:** Canada lags peer countries in time it takes for new medicines to reach patients. Improving the regulatory and policy environment to accelerate approval timelines ensures patients have timely access to treatments while encouraging investment and innovation in Canada.

RECOMMENDATION 2

**SUPPORTING CANADIANS IN NEED IN ACCESSING MEDICINES:** The Pharmacare Act, while well-intentioned, does not align with the government's stated goals of reducing wait times for medicines. Targeting funding at uninsured and underinsured Canadians, while leaving the private market intact, gets more medicines to more Canadians in need.

RECOMMENDATION 3

**PROTECTING INTELLECTUAL PROPERTY (IP) IN CANADA:** Establish a more ambitious IP protection regime that matches or exceeds international competitors.

RECOMMENDATION 4

**INCREASE INVESTMENT IN THE LIFE SCIENCES INDUSTRY IN CANADA:** Increase industry investment to expand domestic manufacturing capacity in Canada.

## INTRODUCTION

Canada's healthcare system was once a source of national pride. While there's still much to be proud of, the reality is that our healthcare system is no longer keeping up with patient needs. Patients deserve timely access to healthcare innovations, including the latest treatments, when they need them.

Canada has the core strengths to be a global leader in the knowledge economy: world-class scientists and researchers, a growing life sciences sector, leadership in artificial intelligence (AI), more than 3,000 ongoing clinical trials, and billions of dollars in recent investments from the research-based pharmaceutical industry.

Innovative medicines and vaccines are among the most effective tools to prevent illness, manage chronic disease, and, in some cases, provide life-changing cures. These innovations not only keep Canadians healthier but also ease pressure 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)[1]. Beyond saving lives, this vaccine generates up to $51.3 million in annual healthcare savings by reducing the number of cases requiring treatment. It also provides an additional $26.2 million in indirect savings to the Canadian economy each year by reducing productivity losses due to illness[2]. Additionally, according to the Adult Vaccines Alliance there is an estimated annual value of $2.5 billion from adult vaccines, including value to the healthcare system and economy[3]. In addition to cost savings, innovative treatments enable Canadians to live longer, healthier, and more productive lives.

Unfortunately, Canadians wait too long for access to the medicines they need, and in some cases, they can't access them at all. Only 21%[4] 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 programs. For rare disease treatments, the wait can be even longer – up to six years more than in the U.S. or Europe, according to the Canadian Organization for Rare Disorders.

Our industry has long been a key driver of healthcare innovation, supporting more than 110,000 high-value jobs, investing $3.2 billion in R&D, and contributing nearly $18.4 billion to the economy each year[5].

Government collaboration is critical to creating policies and regulations that attract R&D and life sciences investment – especially as Canada faces increasing uncertainty in its relationship with the U.S. Investing in the Canadian life sciences sector will help maintain global competitiveness, provide Canadian scientists and clinicians with access to cutting-edge research, and offer patients early access to innovative treatments through clinical trials.

As the federal government develops its budget to build the strongest economy in the G7, Innovative Medicines Canada (IMC) submits this proposal to position the life sciences sector as the key economic driver that it could and should be. By accelerating access to life-saving medicines and vaccines and strengthening IP protections for pharmaceutical innovation, we can build Canada into the economic powerhouse it should be.

[1] Kjaer, S. K., et al. (2020). Final analysis of a 14-year long-term follow-up study of the effectiveness and immunogenicity of the quadrivalent human papillomavirus vaccine in women from four Nordic countries. eClinicalMedicine, 23, 100401. doi: 10.1016/j.eclinm.2020.100401.

[2] 6456_IMC_ValueofMedicines_EFPIA_casestudies_2023_v5.pdf

[3] https://static1.squarespace.com/static/64a5d9ad28fcd800b6d17d4a/t/6716cf23a1822100f5c8b425/1729548068370/Adult+Vaccine+Alliance+-+The+Unmet+Value+of+Vaccines+in+Canada+-+Oct+2024+-+English.pdf

[4] Global Access to New Medicines Report

[5] https://www150.statcan.gc.ca/n1/pub/11-621-m/11-621-m2025004-eng.htm

## RECOMMENDATION 1

### REGULATORY AND POLICY ENVIRONMENT: Canada lags peer countries in time it takes for new medicines to reach patients. Improving the regulatory and policy environment to accelerate approval timelines ensures timely patient access while promoting investment and innovation in Canada.

Breakthrough medicines and vaccines help Canadians live longer, healthier lives, yet only 18% of globally launched new medicines are available through Canadian public drug plans. Additionally, it can take up to two years for critical medicines and vaccines to be available to Canadians on these plans. Canada ranks last in the G7 and 19th out of 20 OECD countries for wait times following regulatory approval. Programs such as the federal pharmacare program – while well-intentioned – create additional red tape inhibiting access to medicines, without addressing the very real problem that some Canadians that are uninsured or underinsured face.

IMC was pleased to see reducing wait times for life-saving medicines, securing Canada's domestic biomanufacturing advantage, and a commitment to examining regulations to reduce red tape as part of the 2025 Liberal election platform. In order to make those commitments a reality, a coordinated, whole of government approach is needed to streamline federal policies affecting treatment access. While provinces and territories administer their own drug programs, federal investment and commitments to regulatory modernization can help strengthen the sector, improve availability, and reduce patient wait times.

We encourage the federal government to work across jurisdictions to better align the Canadian Drug Agency (CDA) and the pan-Canadian Pharmaceutical Alliance (pCPA) to create more streamlined, parallel processes, while increasing the accountability and transparency of these organizations to ensure faster negotiations.

The government should also continue to support conversations that have been taking place between IMC and Health Canada to address challenges that have arisen regarding approval timelines. We see this partnership as a real opportunity to focus on the regulations that are critical for ensuring safety, quality and efficacy, while addressing some of the regulatory burden that does not serve these critical mandates. Work-sharing of regulatory reviews with other partner countries, reliance on trusted foreign regulatory reviews where appropriate, increased efforts to support agile licensing, and other best practices will streamline drug approvals and enable Health Canada to be a global regulatory leader.

## RECOMMENDATION 2

### SUPPORTING CANADIANS IN NEED IN ACCESSING MEDICINES: Targeting funding at uninsured and underinsured Canadians, while leaving the private market intact, gets more medicines to more Canadians in need.

IMC has always supported any and all efforts to increase Canadians' access to new, innovative treatments. To that end, IMC maintains that a fiscally responsible pharmacare program that targets uninsured and underinsured Canadians is a more efficient way of increasing access to medicines across Canada's publicly funded programs.

Canada's pharmacare policy should build on the existing strengths of our dual system of private and public drug coverage. Currently, over 95% of the population has access to either employersponsored or public drug coverage, with 27 million Canadians enrolled in employersponsored plans[6]. Insurance gaps are concentrated across public drug plans in provinces, which presents a clear, feasible way for government to use the remaining funds allocated for pharmacare to ensure access for those who are truly in need of drug coverage. Targeting funds to those who are without insurance protects the private market for those who use it, and allows provinces to determine their needs based on existing coverage gaps. There is a risk of reducing access and delaying coverage for Canadians with private coverage, which is broader and faster.

A fill the gaps approach also ensures that new innovative treatments can still reach patients who would benefit from them, by not restricting patients to a limited formulary, as outlined in the Pharmacare Act presently.

[6] http://clhia.uberflip.com/i/1526931-canadian-life-and-health-insurance-facts-2024-edition/14

## RECOMMENDATION 3

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

With sector-specific tariffs threatened, potentially as high as 200%, the pharmaceutical supply chain is becoming increasingly fragile.

Canada's integration into 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 negatively impact patients on both sides of the border, weaken Canada's life sciences ecosystem, and harm economic prosperity. Actions that make Canada a less attractive destination for therapeutic launches or life sciences investment could have lasting consequences for our healthcare system.

To safeguard access, medicines, vaccines, manufacturing inputs, and packaging materials should be protected from tariff and non-tariff retaliatory measures.

Currently, Canada provides only two years of patent term restoration for regulatory delays, compared to five years in Europe and the U.S.

The U.S. also provides 12 years of data protection for biologics, while Canada offers just eight.

To become a G7 leader in innovation, Canada should provide 10 years of regulatory data protection, and at least five years of patent term restoration. Canada should also remove restrictive eligibility criteria and apply Patent Term Restoration and Patent Term Adjustment consecutively, not concurrently. This will help Canadian biotechnology companies commercialize and scale globally competitive businesses, benefitting Canadians' health and prosperity.

Strong IP protections are essential to continued pharmaceutical innovation and better health outcomes. Canada should fully implement the Patent Term Adjustment (PTA) under the Canada-U.S.-Mexico Agreement (CUSMA) to ensure companies are compensated for patent term lost due to unreasonable delays in patent prosecution.

## RECOMMENDATION 4

### INCREASE INVESTMENT IN THE LIFE SCIENCES INDUSTRY IN CANADA: Increase investment to expand domestic manufacturing capacity in Canada.

The COVID-19 pandemic revealed Canada's vulnerability due the lack of domestic manufacturing capacity for medicines and vaccines. While the government made commitments to invest in the industry during the pandemic, these investments have since declined.

To make Canada more attractive to investors, the government must lead by example. Recent announcements to attract more researchers and reduce regulatory duplication at the provincial and federal levels are encouraging first steps. However, the government should build on this momentum to further encourage private sector investment, bring more treatments to patients, and create more jobs for Canadians.

## CONCLUSION

IMC and its members look forward to strengthening collaboration with the federal government to reduce delays in access to life-saving treatments and grow Canada's life sciences sector. By fostering innovation and investment, Canada can become a global leader in life sciences innovation.

We will continue working with all levels of government and stakeholders to ensure a sustainable healthcare system and timely access to medicines and vaccines for all Canadians.

## ABOUT IMC

Innovative Medicines Canada (IMC) is the national association representing Canada's innovative pharmaceutical industry. The industry proudly supports more than 110,000 jobs, contributes a total of $18.4 billion to the economy, sponsors the majority of clinical trials in Canada, and invests close to $3.2 billion in research and development each year. IMC advocates for policies that enable the discovery, development, and delivery of innovative medicines and vaccines to improve the lives of all Canadians. The association and its members are committed to being solutions-oriented partners in Canada's healthcare system and have contributed more than $30 million towards applied health systems research through the Health Research Foundation (HRF). Guided by the Code of Ethical Practices, all members work with governments, private payers, healthcare professionals, and stakeholders in a highly ethical manner.

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