



INCREASING ACCESS TO INNOVATIVE MEDICINES

LET'S TALK BUDGET 2023

FEBRUARY 10, 2023



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RECOMMENDATIONS SUMMARY

ISSUE

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.

RECOMMENDATION 1

GIVE CANADIANS THE MEDICINES THEY NEED:

Create an environment that makes Canada a priority nation for launching drugs and vaccines.

RECOMMENDATION 2

REDUCE WAIT TIMES FOR PATIENTS:

Address delays in the drug access pathway so Canadians no longer wait two years for life-saving medicines.



INTRODUCTION

The impact of the COVID-19 pandemic has shifted the health landscape in Canada. While the federal government has demonstrated its ability to react to an unprecedented health crisis, doing so has also sharpened the focus on domestic capacity and innovation in the life sciences sector.

Throughout the pandemic, we could not be prouder of our members' collaborative efforts worldwide. From the onset, they worked toward agreements with nations and competitors to increase manufacturing capacity and minimize pharmaceutical supply chain disruption. IMC members demonstrated the industry's value to the world, as the critical importance of reliable access to medicines was brought into focus. More information on our members' contributions in the fight against COVID-19 can be found [here](#).

IMC represents 50 companies that make up the life sciences ecosystem, investing nearly \$1.4 billion in R&D annually, fueling Canada's knowledge-based economy, while contributing nearly \$8 billion to Canada's economy including 55,400 high value jobs across the country. Based on 2020 data from Statistics Canada, the innovative pharmaceutical sector's R&D to sales ratio is up to 10%¹.

Against the backdrop of the pandemic and its devastating impacts, IMC's submission for the Department of Finance's consultations in advance of Budget 2023 presents a path forward that places the priority on Canadian patients and getting them the life-saving medicines and vaccines they need as soon as possible.



¹The Canadian Research and Development Pharmaceutical Sector, 2020, Statistics Canada, <https://www150.statcan.gc.ca/n1/pub/11-621-m/11-621-m2023001-eng.htm> (accessed February 1, 2023)

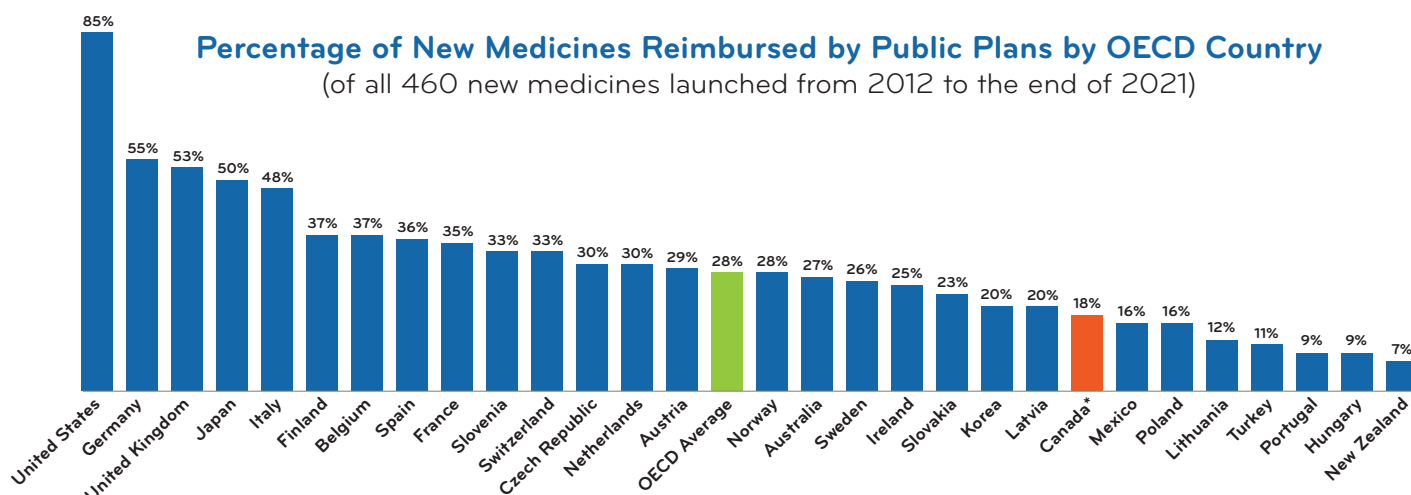
RECOMMENDATION 1

GIVE CANADIANS THE MEDICINES THEY NEED:

Create an environment that makes Canada a priority nation for launching drugs and vaccines.

The discovery, development and delivery of transformative medicines and vaccines to all Canadians help them live longer and healthier lives. According to country-level data on 30 developing and high-income countries between 2000-2009, pharmaceutical innovation accounted for 73% of the increase in life expectancy.²

The benefits of innovative medicines are not something that can simply be expected. As it stands, only 18% of new medicines launched globally are available to Canadians on public plans. That number increases to only 44% when private plans are included.³



*A medicine is considered publicly reimbursed in Canada if 50 percent or more of the population lives in a province where it is publicly reimbursed.

Source: PhRMA analysis of IQVIA MIDAS and U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japan Pharmaceuticals and Medical Devices Agency (PMDA) data. August 2022. Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Data excludes Chile, Colombia, Costa Rica, Denmark, Estonia, Greece, Iceland, Israel and Luxembourg.

²Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-income Countries, 2000-2009', F. LICHTENBERG, Columbia University, https://www.researchgate.net/publication/254435307_Pharmaceutical_Innovation_and_Longevity_Growth_in_30_Developing_and_High-income_Countries_2000-2009 (accessed October 3, 2022)

³PhRMA analysis of IQVIA MIDAS and U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japan Pharmaceuticals and Medical Devices Agency (PMDA) data. August 2022. Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Data excludes Chile, Colombia, Costa Rica, Denmark, Estonia, Greece, Iceland, Israel, and Luxembourg. A medicine is considered publicly reimbursed if 50 percent of more of the population lives in a province where it is publicly reimbursed.

The current unpredictable and uncompetitive pricing environment will further risk product launches and industry investment in clinical trials. Despite recent court rulings that invalidated two of the major amendments to the Patented Medicines Regulations, the implementation of the remaining amendments will have adverse effects on the availability of new medicines in Canada. Specifically, we are very concerned regarding the impact of the Patented Medicine Prices Review Board's (PMPRB) October 2022 proposed changes to its Guidelines.⁴ While implementation was suspended in December, the ongoing uncertainty associated with the Guidelines remains a major source of concern for IMC members.

Further, a recent Conference Board of Canada (CBoC) report indicates that approximately 2.8% of Canadians do not have any form of prescription drug coverage, a decrease from 5.2% in 2016. These data support a policy approach that works to close any residual gaps through targeted investments, for example, to expand the 2021 Prince Edward Island pharmacare investments to help other provinces fill jurisdiction-specific gaps.

Additionally, the government should accelerate its work on a comprehensive rare diseases strategy that leverages the government's progressive commitments of up to \$500 million per year in ongoing funding. Canada remains the only G7 country without a national approach to rare diseases. A comprehensive Canadian strategy should include a standard definition for what constitutes a 'rare disease' in line with our international peers, an accelerated drug review, approval, and access pathway, the use of real-world data, and rare disease centres of excellence.



⁴ '2022 Proposed updates to the PMPRB Guidelines', Patented Medicines Prices Review Board, https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/2022-proposed-updates-guidelines.html?mc_cid=fd574fd1d&mc_eid=50da44c3b5#sec1 (accessed October 7, 2022)

RECOMMENDATION 2

REDUCE WAIT TIMES FOR PATIENTS:

Address delays in the drug access pathway so Canadians no longer wait two years for life-saving medicines.

While availability of new medicines is a significant issue, so is the amount of time Canadians wait for access to approved new medicines.

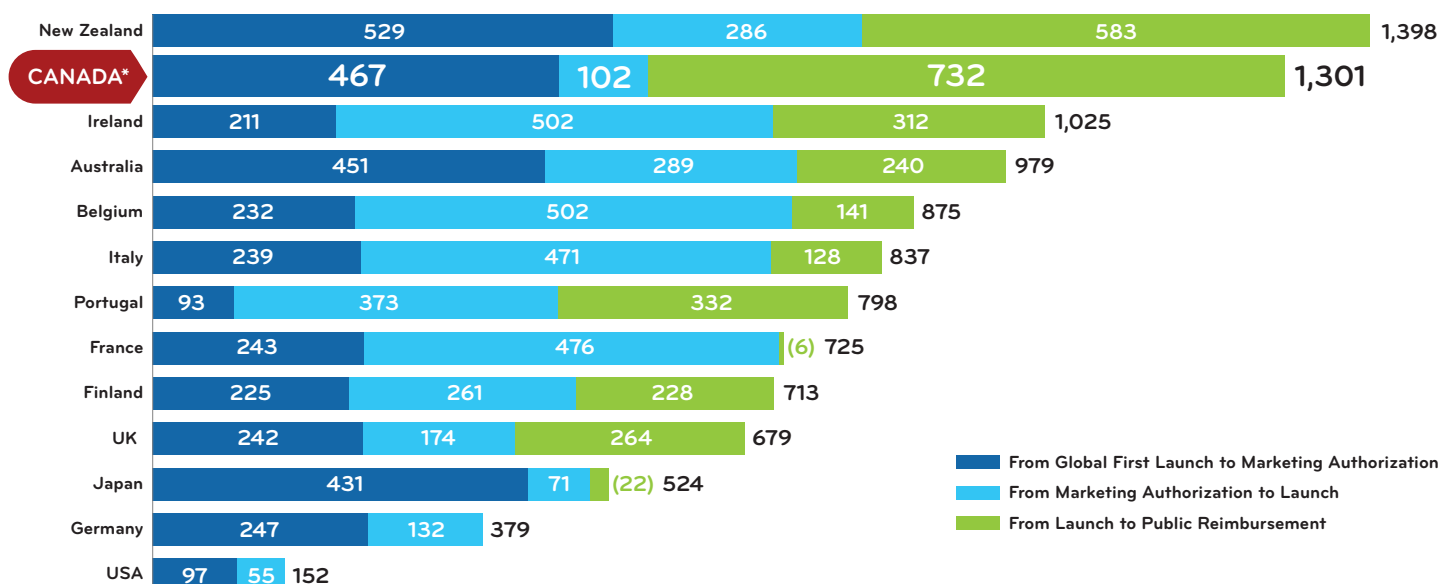
New data indicates that Canadian patients wait an average of 732 days to access a Health Canada approved medicine through a public drug plan, which is twice the average of peer OECD countries.

The delays caused by the various steps in the process are further detailed in Appendix A, the Canadian Drug Access Pathway.

A strong economy begins with healthy Canadians who can actively participate in it. For example, CBoC research into the health and economic impact of access to breakthrough cancer treatments for five tumor types found that if patient had access to new medicines in the last decade, "the potential cumulative benefits would have been up to 226,445 life years gained (the additional number of years of life that a person lives from receiving treatment) and \$5.9 billion in potential economic value".

Number of Days from Global First Launch to Public Reimbursement

(of all 460 new medicines launched from 2012 to the end of 2021)



*A medicine is considered publicly reimbursed in Canada if 50 percent or more of the population lives in a province where it is publicly reimbursed.

Source: PhRMA analysis of IQVIA MIDAS and U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japan Pharmaceuticals and Medical Devices Agency (PMDA) data. August 2022. Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Data excludes Chile, Colombia, Costa Rica, Denmark, Estonia, Greece, Iceland, Israel and Luxembourg.

To ensure many Canadians do not have to wait two years for the new medicines they need, Canadian governments should take a holistic view of delays across the entire access continuum. This continuum includes federal (Health Canada and PMPRB), F/PT (CADTH and pCPA) and provincial (public drug plan) components. Delays arising from any part of the continuum negate efficiencies gained in other parts of the system.

For example, pending improvements to Health Canada's drug approval process are likely to be beneficial, but their impact will be undermined by adverse PMPRB Guidelines changes, health technology assessment recommendations, and finally by prolonged drug negotiation and listing processes. A cohesive approach that considers the wide-ranging implications of legislative and regulatory changes would mitigate these challenges to reduce strain on our healthcare systems.

Canadian governments need to work collaboratively with industry and stakeholders to accelerate patient access to new medicines and vaccines in Canada.



CONCLUSION

As the Government of Canada focuses on finishing the fight against COVID-19, strengthening Canada's economy, and improving the country's healthcare systems, IMC members are looking forward to our continued partnership. We will continue to work collaboratively with all levels of government and stakeholders across the country to ensure the sustainability for our healthcare systems and get Canadians timely access to the innovative medicines they need.

APPENDIX A

CANADIAN DRUG ACCESS PATHWAY



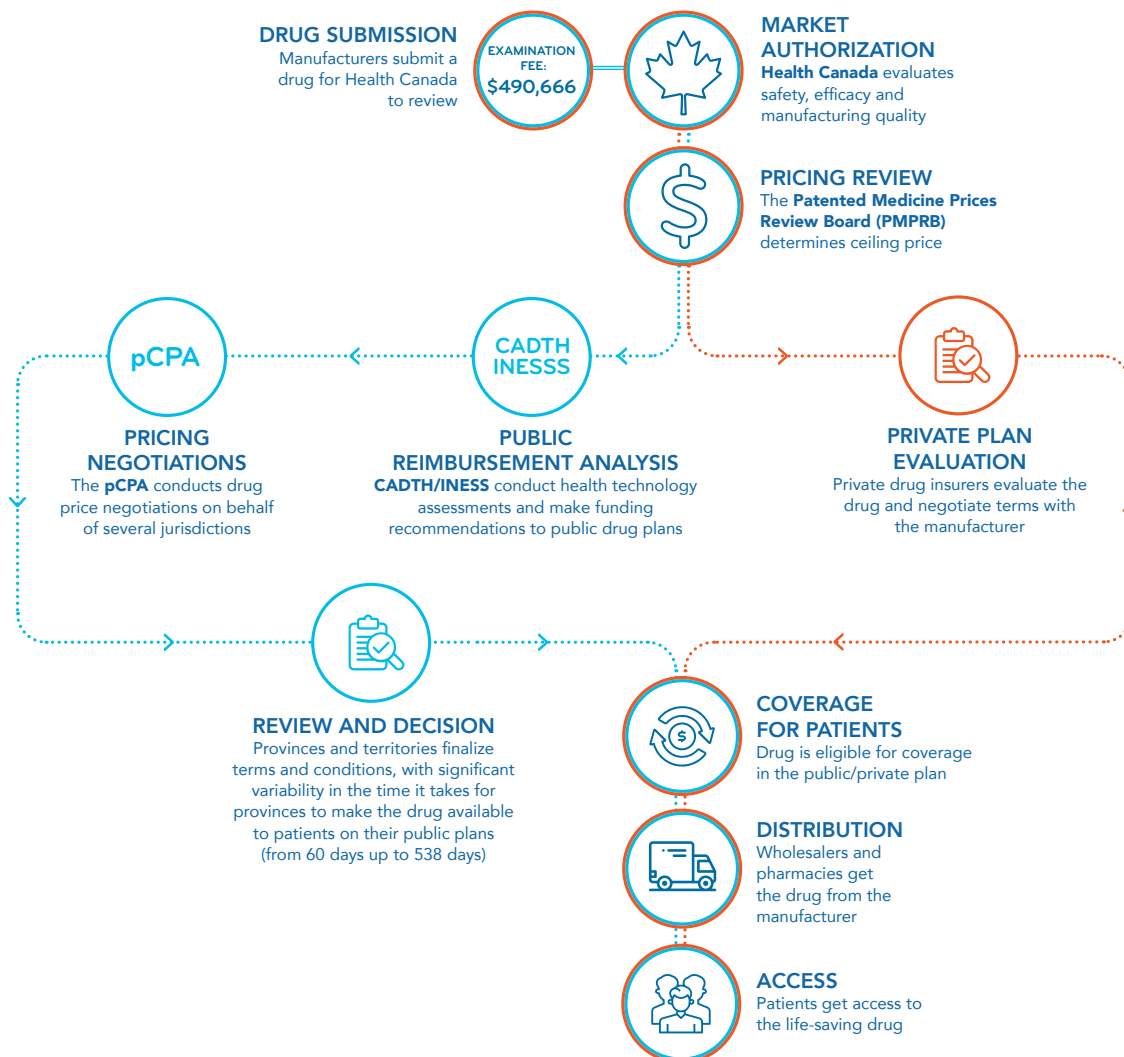
The process for Canadians to access new medicines is extremely complex and involves several different federal, provincial, and territorial agencies. It takes two years following approval (732 days) for Canadian patients to get access to a drug in the public plan, whereas those in the private plan get access to a drug in less than one year (226 days).

PUBLIC PLAN

732 DAYS
from approval to
patient access

PRIVATE PLAN

226 DAYS
from approval to
patient access



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