







September 21, 2020

The Right Honourable Justin Trudeau, P.C., M.P. Prime Minister of Canada 80 Wellington Street
Ottawa, ON K1A 0A2

Subject: Amendments to the Patented Medicines Regulations Require Caution and Collaboration to Protect Canada's Health Research and Innovation Ecosystem, Strengthen Canada's Health Security and Support Canada's Economic Recovery

Dear Prime Minister Trudeau,

On behalf of the undersigned, we would like to commend you and the Government of Canada for your exceptional leadership throughout the COVID-19 pandemic and thank you for your recognition of the critical role of the health research and innovation ecosystem in addressing this public health crisis.

Collectively, our organizations represent hundreds of health- and research-based institutions and organizations across Canada, including clinics, hospitals, universities, research institutes, colleges, health charities and patient groups. Together, we represent millions of patients and tens of thousands of researchers and clinicians who work tirelessly to better understand health and disease and develop new ways of keeping us well.

As health researchers, medical professionals, service providers and advocates, we support the fundamental responsibility of the federal government to ensure that the price of medicines reflects the value they deliver to patients and health systems, and supports affordability and accessibility for all the people of Canada. Reforms to our decades-old pricing regime are needed to reflect changes in technology, healthcare delivery and value assessment, and we appreciate that the amendments made thus far to the *Patented Medicines Regulations* share these goals. It is for this reason that we have come together to respectfully register our grave concerns regarding the Draft Guidelines of the Patented Medicine Prices Review Board (PMPRB).

The purpose of this letter is to request that the government exercise caution and consult more broadly on a carefully managed transition to a set of reforms that are acceptable to health research and innovation stakeholders. There is a real risk of severely damaging the broader health innovation ecosystem, undermining Canada's sovereign health security and ultimately harming all Canadians by restricting access to life-saving treatments. We request that you undertake a broader consultation with the full spectrum of stakeholders who are directly and indirectly impacted by these reforms, including the sectors represented by the undersigned.

Canada must have a vibrant health innovation ecosystem to be globally competitive and strengthen domestic health security. It is a pillar of nation-building. The academic, health system, charitable and biopharmaceutical sectors have built critical partnerships and interrelationships that support clinical research and trials that are essential to giving patients timely access to potentially life-saving medicines

and facilitate the commercialization of discoveries arising from Canada's substantial investments in science. The reforms risk jeopardizing these critical partnerships and severely limiting the health innovation ecosystem's ability to conduct the clinical research that leads to the commercialization of innovative medicines.

It is not our intent here to comment on specific reforms; however, the complexity and scope of the reforms to the PMPRB, along with the absence of clear, consistent data on their impact on patients' health and the publicly-funded health systems, hospitals and research institutes that comprise the health innovation ecosystem, give our organizations pause. We cannot risk limiting patients' access to the life-saving medicines that they need now and compromising Canada's sovereign health security at a time when it is more fundamental than ever. We have to get these reforms right, and any steps we do take need to be implemented with care, caution and a plan to measure and address unintended impacts.

The COVID-19 public health crisis has shed light on the importance of a collaborative, balanced and thriving health innovation ecosystem for pandemic preparedness. This has been a moment of enormous challenge, but also of enormous success. The research community in Canada has been able to respond quickly and effectively to COVID-19 precisely because of the interrelationships between sectors that exist in our health innovation ecosystem, of which the health and biosciences sector is a critical partner.

We have also seen that other health challenges do not disappear during a pandemic; indeed, many chronic diseases and mental health issues have been exacerbated by COVID-19. These combined demands place an inordinate amount of pressure on manufacturers in many industries that have been struggling to manage the pandemic's growing impact on their supply chains, reinforcing the importance of developing resilient supply chains that anticipate, react to and recover from these unexpected events.

Given these ongoing and emerging health threats, it is of vital importance that we preserve the integrity of the health innovation ecosystem and the health and biosciences sector and protect the considerable investments the Government of Canada has made to advance health research in recent years. Our health security and future preparedness as a country demands research and development to advance preventative, therapeutic and diagnostic health technologies and tools in Canada that will help to both improve and protect the health of Canadians.

There is still time for the federal government to engage in a process that not only brings the right groups to the table, but also provides enough time to collect the appropriate data on health and economic impact and outcomes, which inform decision-making. It is only then that we will prevent any unintentional harm to patients and damage to the Canadian health innovation ecosystem and our capacity as a country to innovate, globally compete and nation-build.

We appreciate the work that you, your staff and your Ministers are currently undertaking to address COVID-19 with an evidence-based, science-driven approach. Our organizations are pleased to assist in this process, and we do look forward as a community to planning for a thriving health innovation ecosystem in the future.

Sincerely,

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Colleges and Institutes Canada

Paul-Émile Cloutier President and CEO

HealthCare CAN

Connie Côté

Chief Executive Officer

Health Charities Coalition of Canada

Deborah Gordon-El-Bihbety

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Research Canada

cc. The Honourable Patty Hajdu, Minister of Health

The Honourable Navdeep Bains, Minister of Innovation, Science and Industry The Honourable Chrystia Freeland, Deputy Prime Minister and Minister of Finance

Dr. Stephen Lucas, Deputy Minister of Health

Mr. Simon Kennedy, Deputy Minister of Innovation, Science and Industry

Mr. Paul Rochon, Deputy Minister of Finance

Dr. Mona Nemer, Chief Science Advisor