INNOVATIVE MEDICINES CANADA

2017 PRE-BUDGET SUBMISSION

HOUSE OF COMMONS STANDING COMMITTEE ON FINANCE

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Ottawa, Ontario

55 rue Metcalfe Street | Suite/bureau 1220 | Ottawa ON | K1P 6L5 | 613-236-0455 | innovativemedicines.ca

On behalf of Innovative Medicines Canada and its members, we are pleased to make the following submission to the 2017 pre-budget consultation process.

Innovative Medicines Canada is the national voice of Canada's innovative pharmaceutical industry. We are committed to working with the federal government to ensure Canadian patients have access to the best innovative medicines and vaccines in the world, and to contributing to the long-term sustainability of Canada's healthcare system.

THE VALUE OF INNOVATIVE MEDICINES

Canada's innovative pharmaceutical industry discovers and develops new medicines and vaccines. As an industry, we live to innovate; it's our driving force. Today's pharmaceutical discoveries are leading to improved health outcomes through personalized medicine, with diagnoses, practices and treatments increasingly tailored to individual patients.

For decades, Canadians have benefited these discoveries—cutting edge treatments that can turn chronic, debilitating and sometimes life-threatening illnesses into a thing of the past. Innovative medicines and vaccines have eradicated diseases like smallpox. In just one generation, we have shifted HIV from a death sentence to a manageable chronic illness while research continues towards finding a cure.

Our innovations provide Canadians with value — value to patients and their families, value to our healthcare system and value to Canada's economy.

Discovering new pharmaceutical solutions is a time-consuming, costly and complex process. It involves private sector and university-based researchers, life science companies, significant capital investments, government regulators and patients—all working collaboratively to increase and improve treatment options.

Canada's life sciences sector supports over 34,000 high-quality jobs, many of whom are skilled science, technology, engineering and mathematics (STEM) graduates. Currently, over 1,400 innovative products are in the development pipeline, thanks to a clinical trial capability built up over 30 years.

THE CHALLENGE OF HEALTHCARE SUSTAINABILITY

Recommendation: That innovation is included as a specific objective within Health Canada's mandate to help the department create the appropriate context and perspective to inform its regulatory policies and activities.

Recommendation: That Health Canada study and report publicly on the determinants of healthcare sustainability.

Canada's healthcare system is in a period of rapid change, focused on future sustainability. Sustainability of the healthcare system is a function of many factors, including key mandates, the consolidation of organizational structures, better measurement and reporting, quality improvement efforts, the adoption of digital health solutions, the timely availability of life-saving medicines and vaccines and reduced regulatory delays.

Innovative medicines play a large role in healthcare sustainability. Today, innovative medicines represent 6.4 percent of total national health care costs, down from 8.2 percent a decade ago. These new therapies help Canadians avoid costly hospital stays, invasive surgical procedures and what can sometimes be a lifetime of dealing with chronic illness.

The value of innovative medicines and vaccines to the health system is unquestionable. A 2013 Conference Board of Canada study on the benefits associated with pharmaceutical spending found that, from 2007 to 2012, expenditures of $1.22-billion generated nearly $2.44-billion in health and societal benefits.

At the same time, the demographic shift shows that a lack of access or lack of equal access to services and medicines across all regions of the country is a challenge for too many patients.

Given these ongoing developments and trends, improving Canada's life sciences environment – one that will drive economic success by encouraging investments in innovation—while responding to patients' needs and supporting health system sustainability – is essential.

Unlike other national health regulators such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency, Health Canada's mandate does not include fostering and encouraging innovation with respect to health care products and technologies. The specific inclusion of innovation in its mandate would better inform and guide Health Canada's regulatory responsibilities.

INNOVATION, INVESTMENT & JOB CREATION

At the foundation of a knowledge-based economy is the value of new ideas. In our sector as in others, new ideas lead to new inventions and discoveries that provide Canada the edge to compete on a global scale.

Equally, in ours as in other industries, these inventions and discoveries must be both protected and rewarded. To compete on a global scale, Canada needs to have the legal frameworks and regulations that enable us to attract local and international capital investment and bright minds necessary to compete with similar advanced economies, and also ensure patient access for the products we produce.

Clinical Trials

Recommendation: Continue implementation of the outstanding items from the Clinical Trials Action Plan.

Recommendation: Continue to build support for enhanced data compilation and linkage databases.

Recommendation: Acknowledge the value of clinical trials by capturing all investments as part of SR&ED.

Clinical trials are a critical step in the drug approval process — a step that requires significant investment on the part of the drug developer over a period as long as seven years. With 4500 clinical trials underway as of February 2016, Canada has the ability to host much more.

Countries around the world fiercely compete to attract clinical trial investment and to position themselves as leaders in this area. We have the needed elements to be a leader in clinical trials — a modern health care system, a robust regulatory process, well-trained doctors and clinicians and a heterogeneous population base.

In clinical trial capability, Canada is the only jurisdiction in the world considered equal to the US by the FDA and has a competitive cost advantage to conduct trials. Unfortunately, the value of clinical trials, like so many of our sector's important Canadian investments, is not accurately reflected in the PMPRB's annual mandatory reporting of industry R&D, which is calculated using a limited and outdated R&D definition.

The Innovation Agenda

As a sector intrinsically entwined in the innovation process, we strongly support the federal government's creation of a new innovation agenda for Canada and we will be actively engaging in the consultation process being headed by the Minister of Innovation, Science and Economic Development.

The life sciences sector is a natural partner in these efforts, and we commit to continue to work with the federal government to strengthen Canada's performance on innovation in order to develop our knowledge-based economy.

As part of these efforts, we look forward to identifying a new vision of industrial R&D in Canada, to attract new investments to this country. Currently, our industry faces a unique hurdle, being held to a nearly 30-year old definition of R&D that does not accurately capture the significant investments our members make in this country, as evidenced by the collaborations and investments in partners such as MaRS and JLABS in Toronto, the NeoMed Institute in Montreal, and the Centre for Drug Research and Development in Vancouver.

Comprehensive Economic and Trade Agreement (CETA)

Recommendation: That the Government of Canada take every effort to ensure the ratification of CETA and the implementation of an innovator right of appeal and patent term restoration consistent with both the letter and the spirit of the treaty.

We strongly applaud the efforts of the federal government to move CETA through to a successful conclusion. Finalizing CETA will unlock access to the world's largest common market of 550 million consumers and spur annual economic activity of $12-billion.

Aligning our intellectual property (IP) protection regime with those of our key trading partners is a matter of competitiveness and reputation for Canada. The more Canada is aligned with other countries, the more we will compete effectively in the worldwide race for life science investments in research, clinical development, biotechnology and commercialization of innovative medicines. Currently, Canada attracts about one percent of total global research investments. Our objective is to build a Canadian commercialization capability—to engage with investors in this country to take products to market for the benefit of patients.

For our sector, and subject to proper implementation, the changes proposed in CETA should restore some balance by giving innovators a right of appeal equivalent to the one that exists for generic companies. The changes should also provide increased fairness by restoring for innovators some of the time lost to clinical and regulatory delays —up to two years—between the filing date of patent applications and the date when a pharmaceutical product is granted market authorization. Various forms of patent restoration have already been implemented in almost all other developed nations; this measure within CETA will help Canada to better compete for international life sciences research and investment.

The continued growth of regulatory barriers

Recommendation: That appropriate federal departments review their drug evaluation and approval processes to find efficiencies, in order to improve patient access to new medicines.

While we applaud the improvement of IP protections promised by CETA, these benefits stand to be diminished by the addition of bureaucratic barriers that extend the time between submission to the federal government of newly discovered medicines and vaccines and their ultimate availability to benefit patients.

Beyond the necessary Health Canada safety approval process, there are additional time-consuming hurdles to be surmounted. These include the Patented Medicine Prices Review Board (PMPRB) review, health technology assessments, price negotiations through the Pan-Canadian Pharmaceutical Alliance (pCPA), and, finally, the negotiation of product listing agreements with individual federal drug plans, provinces and territories.

As it stands today, it takes 449 days on average, even after Health Canada approval, before a patient can access a new medicine on a public drug plan. This delays access to the benefits of new medicines and vaccines for Canadian patients, and also erodes the already limited time that innovative companies have to recoup their significant investments in R&D, clinical trials and regulatory approval processes.

We believe that greater regulatory efficiencies and harmonization of drug reviews with other reputable jurisdictions will result in faster access to medicines for Canadian patients, and will also help to preserve scarce resources at Health Canada for other priorities.

The Patented Medicine Prices Review Board (PMPRB)

In recent documents, the PMPRB has raised a number of public policy issues related to pricing and affordability of patented medicines in Canada, and is proposing that changes be made to pricing guidelines and/or regulations, as well as a potential change to the current mandate of non-excessive pricing to affordable pricing.

The PMPRB exercises its statutory mandate by setting ceiling prices for all patented medicines sold in Canada. Through a variety of mechanisms, such as through the Canadian Agency for Drugs and Technologies in Health, the Common Drug Review, pCPA and Product Listing Agreements, industry and public payers, including federal, provincial and territorial governments have collectively and effectively addressed the affordability of medicines. As a result of these measures and negotiations, these payers have been able to secure preferential pricing for their public drug plans, to achieve better value for their vulnerable citizens.

Innovative Medicines Canada believes that all Canadians should have access to the medicines they need without affordability being a barrier. We are open to exploring new collaborative models to meet access, affordability and budget sustainability, but believe that expanding the PMPRB's mandate is not the right method to address these important issues. We will be presenting our views to the PMPRB consultation review, in addition to discussing these issues with Canadian governments and other stakeholders.