INNOVATIVE MEDICINES CANADA

2018 PRE-BUDGET SUBMISSION

HOUSE OF COMMONS STANDING COMMITTEE ON FINANCE

August 4, 2017

Ottawa, Ontario

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Innovative Medicines Canada, on behalf of its members, is pleased to participate in the House of Commons Standing Committee on Finance's 2018 pre-budget consultations and to provide commentary on the committee's theme of productivity and competitiveness, specifically as it relates to Canadian businesses.

ABOUT INNOVATIVE MEDICINES CANADA

Innovative Medicines Canada is the national voice of Canada's innovative pharmaceutical industry, representing almost 50 companies, from fledgling startups to large, established firms. 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.

SUMMARY OF RECOMMENDATIONS

We recommend that the Government continue to pursue legislative, regulatory and policy initiatives that demonstrate meaningful commitments to strong intellectual property (IP) protection, innovation, and appropriate reward for value in Canada's biopharmaceutical industry.

We recommend that the Government amend the Patented Medicine Prices Review Board (PMPRB)'s measure of pharmaceutical research and development (R&D) in Canada to include the full breadth and depth of pharmaceutical industry investment in Canada.

We recommend that the Government, through Health Canada and the Canada-United States Regulatory Cooperation Council, review the drug evaluation and approval processes to find efficiencies and opportunities for harmonization.

PRODUCTIVITY IN CANADA'S LIFE SCIENCES SECTOR

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.

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

Our industry takes pride in investing in Canada: in 2015, we invested just under one-billion dollars in Scientific Research and Experimental Development tax credit (SR&ED)-eligible R&D, and millions more in scaling-up, venture capital (VC) and partnerships with Canadian biotech companies.

As an industry, we are learning to work in different ways, to create and collaborate new models for innovation within the emerging life sciences ecosystem. It's a new and dynamic set of relationships that harness multiple discovery inputs through a diversity of partnerships—among multinationals and start-up companies, universities and hospitals, the public and private sectors—all focused on the continuum that

discovers, nurtures and develops new products. The necessary links between pharmaceutical companies and Canadian biotech companies are also growing.

In the recent report from the Advisory Council on Economic Growth, Canada's life sciences sector is identified as an economic driver of our economy – and with the right sector-specific solutions, it can be even more competitive on a global scale. As an industry, we are keen to pursue this objective with the Government of Canada.

A significant part of building Canada's strength in the life sciences is to foster a strong foundation in fundamental, or discovery, research. Our industry could not grow and continue its work without the first steps that Canadian researchers take in basic research.

In addition, a study into the industry's economic impact in Canada is currently being conducted by an independent third-party firm. We would be prepared to share this information with the Committee, if interested, once available.

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 inventions and discoveries that provide Canada the edge to compete on a global scale.

In particular, we commend the Government of Canada for building on this through the commitments in Budget 2017 for the Innovation and Skills Plan. Our industry is pleased to continue to work with the government to see this plan realized.

Canada is a nation of innovators. Our members understand the opportunity that innovation presents every day, across the country. We want to ensure that the life sciences sector can continue to grow, providing high-quality jobs to Canadians, attracting investment in research and development and finding the next generation of medicines.

Equally, in ours as in other industries, these inventions and discoveries must be both protected and rewarded. To engage 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.

To increase the productivity and competitiveness in the life sciences sector in Canada, Innovative Medicines Canada puts forward a series of recommendations for Budget 2018, focused on IP, R&D and regulatory competitiveness.

INTELLECTUAL PROPERTY

Aligning our 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.

We await the provisional application of the Comprehensive Economic and Trade Agreement (CETA) with the European Union, and note that changes to Canada's IP regime through CETA – if implemented in an effective manner and true to the spirit and intent of negotiations – will help Canada to better compete for international life sciences research and investment.

As Canada enters into talks regarding the renegotiation of the North American Free Trade Agreement (NAFTA), we encourage the federal government to continue to pursue legislative, regulatory and policy initiatives that demonstrate meaningful commitments to strong IP protection, innovation, and appropriate reward for value in Canada's biopharmaceutical industry. The proper renegotiation of these commitments will determine how effective these measures will be in both sending a positive signal to the international industry with respect to doing business in Canada, as well as supporting the development of innovative medicines in Canada.

RESEARCH AND DEVELOPMENT

Global changes in how pharmaceutical companies innovate have led to different investment models over the past 25 years—moving from companies with internal R&D infrastructure in multiple countries, to external financing and research partnerships through direct investments, venture capital funds and other mechanisms.

For our industry, this growing network of partnerships and collaboration represents tens of thousands of jobs and an investment of more than $20 billion in Canada over the past two decades. Our large pharmaceutical members play a catalytic role in innovation through partnerships with smaller biotechnology companies and publicly-funded institutions.

In terms of commercialization, across the country the NEOMED Institute, MaRS Innovation and the Centre for Drug Research and Development are but a few of the leading organizations that benefit from industry partnerships to work on commercializing new, potentially life-saving and life-changing therapies. Industry is also stimulating R&D through VC funds that allow industry to gain access to promising technologies and develop them, while minimizing risk.

These new forms of R&D and sizeable investments in Canada, however, are not captured by the government body that measures pharmaceutical R&D annually – the Patented Medicine Prices Review Board (PMPRB).

For example, discovery research conducted by a researcher working within a pharmaceutical company's laboratory would be considered an R&D expenditure. On the other hand, clinical trial research, carried out by a contract research organization, but funded by the same pharmaceutical company, would not be counted as an R&D expenditure. Both types of R&D are company-funded and create jobs in Canada, yet only one is included in the PMPRB's annual reporting of pharmaceutical R&D in Canada.

This disparity hurts Canada's competitiveness and the ability to attract global investment. Having the government's acknowledgement of industry investment goes a long way to inspire confidence in global investors.

Despite these challenges, the CEOs of our member companies are strong global advocates for increased R&D in Canada. We have the same goals as the federal government in seeking more foreign investment in

Canada, but it is critical we can demonstrate to our global research offices that this country offers a competitive environment in which to invest.

It is not a question of whether industry investments can be offset by SR&ED tax credits, but rather creating a mechanism that acknowledges that the life sciences industry's investments in Canada go beyond the limited SR&ED definition. For this reason, we ask that the PMPRB's measure of pharmaceutical R&D in Canada is revised to include the full breadth and depth of pharmaceutical industry investment in Canada.

REGULATORY EFFICIENCIES

A strong regulatory regime is the backbone of ensuring patient safety when it comes to new medicines. Canada has a strong reputation the world over for the quality of our regulatory processes

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 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 resources at Health Canada for other priorities.

Regulatory harmonization initiatives, for example, to better align Canada with European Medicines Agency (EMA) or Food and Drug Administration (FDA) standards, would significantly lessen the burden of those filing for regulatory approvals, while at the same time ensuring that safety is not jeopardized.

In particular, both the FDA and EMA accept external scientific evidence as a standard part of the regulatory review process, in addition to permitting the introduction of new data during regulatory reviews. Both of these mechanisms ensure that regulatory reviews are based on the best, most current scientific information possible.

Canadian patients could also experience improved timely access to important new therapies if external scientific advice and new data were accepted in ongoing drug approval processes.

We recommend that the federal government, through Health Canada and the Canada-United States Regulatory Cooperation Council, review the drug evaluation and approval processes to find efficiencies and opportunities for harmonization, in order to accelerate access to new medicines for patients while at the same time ensuring safety and efficacy of medicines.