INNOVATIVE MEDICINES CANADA

2016 PRE-BUDGET SUBMISSION

HOUSE OF COMMONS STANDING COMMITTEE ON FINANCE

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On behalf of Innovative Medicines Canada and its members, we are pleased to make the following submission to the 2016 pre-budget consultation process.

Innovative Medicines Canada is the national voice of Canada's innovative pharmaceutical industry. We are proud to be an integral part of this country's healthcare system and are committed to working with the federal government to ensure Canadian patients have access to the best innovative medicines and vaccines in the world.

THE VALUE OF INNOVATIVE MEDICINES

Through our focus on innovation and through the delivery of new pharmaceutical discoveries, our products provide Canadians with value — value to patients and their families, value to our healthcare system and value to the federal and provincial economies.

As Canada's innovative pharmaceutical industry, our job is to discover and develop new medicines and vaccines. For decades, Canadians have benefitted from these discoveries. Innovative medicines and vaccines have eradicated diseases like polio and smallpox. In just one generation, we have shifted HIV from a death sentence to a manageable chronic illness and research continues towards finding a cure.

Innovative medicines and vaccines also make substantial contributions to our healthcare system. Today, innovative medicines represent 6.4 percent of total national health care costs, down from 8.2 percent a decade ago. Innovative medicines are an investment that delivers significant return. New therapies, for example, help Canadians avoid costly hospital stays, invasive surgical procedures and what can sometimes be a lifetime of dealing with chronic illness.

Innovative pharmaceutical companies are also a critical part of the Canadian economy. Canada's life sciences sector supports over 34,000 high-quality jobs, contributes over $3-billion to our economy annually and has over 1,400 innovative products in development.

LIFE SCIENCES INNOVATION

As Canada looks to diversify its economy, a thriving innovative life sciences sector is imperative. Around the world, the life sciences sector is projected to grow at an annual rate of 9 percent. We need to ensure that that economic growth takes place here at home.

The drug development process is lengthy — taking as much as ten to fifteen years — and costs on average more than $2.6-billion for each new medicine. It involves partnerships between the private sector, university-based researchers and life sciences companies, and it draws in significant capital investments. With the right regulatory, financing and intellectual property policies, we can encourage growth in life sciences research and development here in Canada and we can foster more investment in our country.

The current global spending on life sciences research and development is about $123-billion per year. Of that figure, Canada attracts just over $1-billion today. Working together, we have the potential to grow this figure and to attract more investment to support research, development and commercialization in Canada

Life Sciences Policy Framework

To stimulate the discovery and commercialization of life science research in Canada, we encourage the creation of a federal life sciences policy framework that incorporates and recognizes innovation and health system sustainability in policies related to Innovation, Science and Economic Development Canada and Health Canada.

Economic growth in our life sciences sector will not be achieved through any one specific initiative, but rather through a series of concerted and coordinated actions that build critical research infrastructure, support basic research and commercialization and foster partnerships between all of the key stakeholders and sectors, both public and private. Establishing a policy and funding framework that supports Canadian research and that enables and encourages the development of Canadian technologies and innovations in Canada is a significant part of this.

Research Funding

At the root of Canada's life sciences sector is research.

Research in the life sciences sector has rapidly shifted over the past decade. Our industry's R&D model has shifted from traditional intramural investment taking place in company labs, to external research and commercialization partnerships, allowing our member companies to tap into the vast network of academic institutes, independent researchers, teaching hospitals, incubators and innovation clusters that are found across the country. As a sector, we now invest more than $1-billion each year in Canada's life sciences sector often using these innovative investment models.

We recommend that the federal government also continue to stimulate the Canadian life sciences economy through increased funding for Canadian life sciences research organizations such as the tri-councils (CIHR, NSERC and SSHRC), the Canadian Foundation for Innovation, the Centre for Drug Research and Development and Genome Canada. These investments will allow Canada to support and promote research and commercialization initiatives throughout the discovery lifecycle.

Clinical Trials

An area of great potential for Canada life sciences sector is clinical trials. 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 that could last as long as five to seven years. Clinical trials are an area of significant potential economic development for Canada. Additionally, patients exposed to clinical trials have the benefit of early usage of innovative pharmaceutical products.

Countries around the world are vying to attract clinical trial investment and to position themselves as leaders in this area. Canada has that potential as well. Many of the elements needed to be a leader in clinical trials already exist — a modern health care system, a robust regulatory process, well- trained doctors and clinicians, an a heterogeneous population base. To elevate ourselves from "middle of the pack" to world class we recommend continuing to implement the outstanding items from the Clinical Trials Action Plan.

Intellectual Property

Intellectual property is critical to ensure innovation. Patents and data exclusivity enable innovative companies to recoup the huge investments involved in creating new medicines and protect scientific discoveries during the research process. A patent is obtained very early in the drug development process. Most of the patent life is expended during the research and regulatory approval process. Once a drug is approved, the actual length of market exclusivity in Canada is typically just seven to nine years.

To ensure we are globally competitive, Canada's intellectual property regime must meet or exceed the standards of our competitors. Through implementation of measures in major trade agreements, such as the Comprehensive Economic and Trade Agreement (CETA) with the European Union (EU), Canada is working to ensure Canadian researchers have the same protections as researchers in other major markets. We therefore recommend that the government approve implement the CETA as soon as possible.

The potential for progress under CETA, while welcome, has been partially overshadowed internationally by a series of court interpretations related to patent utility— interpretations that are out of step with the utility standard applied in other countries, such as the U.S., Japan and in the EU. As of today, 26 innovative products have lost their Canadian patents prematurely due to these interpretations, adversely affecting healthcare and economics. We recommend that the federal government work with our industry on this and other issues to ensure we maintain a stable and competitive intellectual property system.

ACCESS TO MEDICINES

According to the World Health Organization (WHO), access to medicines and vaccines are a key component to a quality health system. Canadians must have access to the medicines they need when they need them. Unfortunately, this is not always the case. We believe that, together, we can work through these challenges.

Quality of Drug Listings

Across Canada's public drug plans, there is wide disparity in both the quality and time to listing.

In 2014, only 43 percent of new medicines were available across provinces comprising at least 50 percent of the national public drug plan population. At the same time, the average wait from national marketing approval (by Health Canada) to public drug plan reimbursement was 462 days, ranking Canada 16th of 18 countries.

We recommend that the federal government leverage its new membership in the pCPA and the upcoming Health Accord discussions, to play a leadership role in identifying ways to reduce time to listing for public drug plans and to improve the availability of drugs to Canadians. This could include identifying greater efficiencies in the HTA and pCPA listing processes. We commit to working with you to make this happen.

Health System Sustainability

We recognize that health care systems are under pressure. Representing just 6.4 percent of total health care costs, we believe innovative medicines provide significant value to the health care system and can be an important tool in managing overall health system costs. With that, the value of innovative medicines should be considered more strongly when setting healthcare budgets. The investment in innovative pharmaceutical

products often means cost savings or, in the case of curative drugs, the elimination of costs in other parts of the health care system.

In Canada, innovative medicines are priced according to the value they deliver to Canadians and to Canada. This value is determined in comparison with other available treatments and on how the new medicine will reduce or negate the need for other more expensive and invasive interventions like hospital stays and surgeries.

Canada's Patented Medicine Prices Review Board (PMPRB) protects the interests of Canadians by ensuring that the prices of patented medicines sold in Canada are not excessive. Since 1994, Canadian patented medicines prices have been, on average, consistently below the median of international prices, and in 2014 (the latest year for which data is available) Canadian prices were 13 percent below the international median. The price of innovative medicines did not increase in 2014, and over the past 22 years, annual changes in the prices of innovative medicines have been, on average, negative.

We understand that the health care system is complex and that there are no simple answers to the pressures faced by health budgets. We encourage a discussion that recognizes both the realities of drug prices in Canada as well as the proven value that our products provide. We also remain committed to being part of that discussion and to working with the federal and provincial governments to identify new models that recognize the value of innovative pharmaceutical products and that help ensure these products are made available to the Canadians that need them.

Rare Diseases

Rare diseases present unique problems for pharmaceutical innovators. The small size of patient populations makes it scientifically more difficult to clinically test and to demonstrate the safety and efficacy of medicines. Additionally, with more complex products and smaller patient groups, it can be economically difficult to successfully develop and commercialize drugs for rare diseases. Unique policies and supports are required.

We recommend that the federal government implement a new rare disease strategy. Canada is one of just a few developed countries that do not have a specific policy to address the needs of people living with rare diseases. A rare disease strategy must support the research and development of drugs for rare diseases – including special provisions for market exclusivity similar to those that exist in other countries such as the United States, the European Union, Taiwan and Japan, and that recognize the increased costs and longer timelines inherent in developing these products. A rare disease strategy must also ensure the process for reviewing and approving drugs for rare disorders reflects the unique nature of the products and the patient groups and must ensure that, ultimately, patients are able to access the products once they have been commercialized.