



FAMILY OF COMPANIES IN CANADA

August 2, 2017

Hon. Wayne Easter, P.C., M.P.
Chair, Standing Committee on Finance
House of Commons
Ottawa, Ontario
K1A 0A6

Re: Johnson & Johnson Family of Companies in Canada Recommendations for the 2018 Federal Budget

Dear Mr. Easter,

On behalf of the Johnson & Johnson Family of Companies in Canada (J&J), I would like to thank you for the opportunity to provide input into the federal government's pre-budget consultations for the 2018 federal budget.

J&J is a leader in Canada's health care sector, active in researching, developing and manufacturing consumer health care products, pharmaceuticals, medical devices and diagnostics. Our five businesses in Canada employ more than 2,500 Canadians and are committed to improving the health and well-being of Canadians every day.

Our vision is to enrich the health and wellness of every Canadian every day. J&J is committed to leading our industry's support of sound public policies which support increased competitiveness in North America, improve the health and safety of Canadians and achieve a sustainable health care system. Collaboration between the federal government and key stakeholders, such as industry, are critical to developing and implementing strong public policies.

Our submission focuses on competitiveness and urges the federal government to establish a vision and foundation for a world-class healthcare system that is focused on optimal patient outcomes and establishes Canada as a leader in the development and adoption of innovative therapies and interventions.

Thank you for the opportunity to provide you with our views on Budget 2018. Should you have any questions regarding J&J's submission, please do not hesitate to contact me directly at 416-301-7352 or at lbabiak@its.jnj.com.

Sincerely,

Dr. Lesia M. Babiak, BscPharm, PharmD, MBA
Executive Director, Worldwide Government Affairs & Policy (Canada)
Chair, Government Affairs Council

Johnson & Johnson, Family of Companies in Canada

Canada: Home to a World-Class Healthcare System that Recognizes the Value of Innovation

In Budget 2018, the federal government should establish a vision and foundation for a world-class healthcare system that is focused on optimal patient outcomes and establishes Canada as a leader in the development and adoption of innovative therapies and interventions.

In Budget 2017, the Government of Canada recognized the potential of the life sciences as a high potential economic driver and included the sector in its Innovation and Skills Plan to expand growth, create jobs and make Canada a leading centre for innovation.

Successful execution of this plan requires that healthcare policy be addressed by a wholistic government strategy. This strategy needs to align the goals of the health portfolio and our health procurement policies with the goals and aspirations of Canada's Innovation and Skills Plan, and actively engage all stakeholders in the healthcare system, including the innovative biopharmaceutical and medical technology sectors.

However, proposed changes to the *Patented Medicine Prices Regulations* threaten to undermine Canada's efforts to realize its ambition to be a global leader in life sciences innovation and may dampen growth of Canada's innovative health and bio-science companies.

The proposed regulations will create a more complex and uncertain pricing environment that will cause global companies investing in innovative medicines to make business decisions that will directly and negatively impact access to new medicines by Canadian patients. For example, there will be reduced investment in clinical trials in Canada, fewer or delayed launches of new medicines in Canada, and less ability to negotiate confidential rebates with payers; all resulting in fewer innovative medicines being made available to Canadian patients.

Longer term, these proposed changes will stifle the potential of Canadian researchers and start-up bio-science enterprises by making it more difficult and perhaps even impossible, to commercialize their innovations at home, while Canadians fall further and further behind in gaining access to new medicines. The absence of new therapies or major delays in introduction of such therapies to the market will also impact Canada's ability to attract clinical trials

Despite Canada's strengths in economic performance, including leading the G7 in economic growth for the past decade, significant action to reduce the prices of patented medicines in Canada will send a strong signal to the global biopharmaceutical industry that Canada does not value an innovation economy and Canada risks slipping to the middle of the pack of the OECD in terms of access to innovative medicines. Canadians cannot afford to have an OECD median mindset when funding health care and innovation if we want to continue to lead the G7 in economic growth. Our health system must recognize the value that our life sciences innovation brings to our health care system and the health, wealth and productivity of Canadians.

As the Government of Canada implements its economic growth and innovation agendas with a focus on high potential sectors like the health and bio-sciences sector, a wholistic lens must be applied by government to the proposed changes to the patented medicines pricing regime to ensure that the goals of innovation are congruent with those of a world-class healthcare system that establishes Canada as a leader in the development and adoption of innovative therapies and interventions.

Innovation – Supporting the Life Sciences Sector

In Budget 2018, the federal government can build on the progress made in Budget 2017 by catalyzing the health and bio-sciences sector in Canada's innovation economy and realizing the potential of this high-growth sector.

The life sciences ecosystem can harness the power and energy of health care start-up companies, as well as recognize that established, multinational corporations, like Johnson & Johnson, can bring critical financial capital, infrastructure and expertise to Canada in research and development. Encouraging this synergy will accelerate commercialization, helping Canadian inventions grow into successful Canadian companies.

Budget 2018 must follow through on implementation of the federal government's Innovation and Skills Plan to grow this high potential sector. J&J supports establishing an Economic Strategy Table focused specifically on the life sciences that is inclusive of all stakeholders in the ecosystem (including biopharma and medtech), and accelerates research and development by supporting a life sciences supercluster in the Innovation Superclusters Initiative.

International Trade

Implementing the Canada-European Union Comprehensive and Economic Trade Agreement (CETA)

Conclusion of the Canada-EU CETA signalled an important improvement in the policy environment for the life sciences sector. The enhancements to the intellectual property (IP) regime in Canada in CETA sent a positive signal to the innovative life sciences sector that Canada recognized the value of innovation and investment in this high potential sector. Since the signing of CETA, J&J has committed approximately \$1 billion to a number of initiatives that contribute to and attract global life sciences investments to Canada.

Following the subsequent ratification of Canada's implementation legislation, Bill C-30, and the announcement of the provisional implementation of CETA on September 21, 2017, draft regulations were republished in the Canada Gazette dated July 15, 2017 for a 15-day comment period, ending on July 30, 2017.

J&J is deeply concerned that Canada's implementation of CETA commitments as published in the Canada Gazette, risk undermining the CETA outcomes and the benefits obtained through years of negotiation and undermine the spirit of the Agreement.

Combined with a lack of transparency regarding the proposed regulations and the wholly inadequate 15-day comment period, J&J urges the Government of Canada to delay provisional implementation of CETA until two critical amendments are made:

1. The proposed *Certificates of Supplementary Protection Regulations* should be amended to allow for filing Canadian new drug submissions within three years (rather than the currently proposed one year) of any first international drug submission filing for the same drug (in any of the EU, U.S., Australia, Switzerland or Japan); and
2. The proposed *Patented Medicines (Notice of Compliance) Regulations* should be amended to provide a 30-month statutory stay, rather than the proposed 24-month stay.

Delaying implementation will also enable Canada to apply a more appropriate consultation period for stakeholders to review both the CSP Regulations and PM(NOC) Regulations that allows engagement in an open and transparent manner that ensures the implementation of CETA truly reflects the spirit of the Agreement and finds solutions for enhancing the competitiveness of Canada's biopharmaceutical sector.

Renegotiating the North American Free Trade Agreement

J&J supports the modernization of the North American Free Trade Agreement (NAFTA) with the United States and Mexico. Free trade with the United States and Mexico has had a positive benefit for the Canadian economy and jobs and these benefits must continue under a renegotiated NAFTA.

A modernized and renegotiated NAFTA must ensure a stable, predictable, and competitive business environment for the economy of today and of the future. This is key to ensuring that Canada maintains its

position as a G7-leading economy and creates the conditions for high-potential sectors, like Canada's life sciences sector to grow and flourish.

Consulting with the business community is key for the federal government as it prepares to enter negotiations and as negotiations proceed. It is critical that the consequences of choices made in the context of negotiations are fully understood, particularly in highly regulated industries. J&J stands ready to engage with the federal government on its own and through its trade associations to provide insights and assistance to Canada as the next chapter in North American trade policy is written.

Evolution of the Regulation of Health Products

Transparency

In recent years, there has been a significant shift in the legislative and regulatory oversight of health products, with government committing to greater transparency and openness as a way to strengthen trust in regulatory decision making.

For manufacturers, this shift has come with added costs as the regulatory burden has increased to meet new levels of transparency and oversight. As the federal government improves access to timely, useful and relevant information for Canadians across departments, J&J encourages the federal government to create a regulatory coherence office to ensure that transparency measures are implemented across government in a predictable manner while ensuring appropriate checks and balances are in place to prevent the hindrance of industry's ability to innovate and compete in the global market.

Innovative and Sustainable Solutions Require Inclusive Consultation

The evolving regulation of health products poses new challenges to both regulators and manufacturers who each face their own unique sets of opportunities and challenges in this rapidly-changing environment.

Striking a balance between enhanced regulatory oversight and an innovative economy that enables inclusive growth requires a full multi-stakeholder consultative approach premised on ongoing, open engagement and meaningful dialogue. Such a consultation process will create opportunity for innovative and creative solutions to policy challenges and result in a more inclusive and sustainable solution for Canadians while ensuring that our innovative life sciences sector remains competitive and continues to thrive.

It takes courage and leadership to identify common goals and resolve conflicts among stakeholders to achieve an outcome that fully meets the needs and expectations of Canadians. J&J Canada encourages the federal government to engage in meaningful dialogue with all stakeholders in the healthcare and life sciences ecosystem – provincial and territorial governments, patients, industry, researchers and insurers – to collaborate and find viable solutions to these challenges that positively impact the health and well-being of all Canadians and our economy.