Johnson & Johnson
FAMILY OF COMPANIES IN CANADA

June 28, 2017

Hon. Jane Philpott, P.C., M.P.
Minister of Health
70 Colombine Driveway
Tunney's Pasture
Postal Location: 0906C
Ottawa, Ontario
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Email: Hon.Jane.Philpott@Canada.ca

Re: Proposed Amendments to the *Patented Medicines Regulations*

Dear Minister Philpott,

The Johnson & Johnson Family of Companies in Canada ("J&J") is a leader in Canada's health sector, researching, developing and manufacturing consumer health and personal care products, breakthrough pharmaceutical medicines and medical devices. J&J consists of five businesses employing more than 2,500 employees across Canada.

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 enable increased competitiveness, advance innovation to improve the health of Canadians and make life-changing and sustainable differences in human health. Collaboration between the federal government and key stakeholders, such as industry, is critical to achieving this goal.

In the spirit of consultation and open dialogue, Johnson & Johnson is sharing its views on the proposed amendments to the *Patented Medicines Regulations*. J&J fully supports the submission made by Janssen Inc., representing our pharmaceutical companies in Canada, to the consultation paper on proposed amendments to the *Patented Medicines Regulations.*

Complementing the views expressed in that submission, J&J encourages the Government of Canada to consider the broader impact of the changes proposed and ensure they align with policy goals addressing the affordability, accessibility and appropriate use of prescription drugs. The impact should also be considered through the lens of its impact on innovation and trade policies. It is critical that the proposed amendments do not undermine Canada's efforts to realize its ambition as a global leader in innovation and vision of growth of Canada's innovative health and bio-science companies.

Prescription Drug Affordability: Policy actions must align with intent

In your remarks to the Economic Club of Canada on May 16, 2017, changes to the Patented Medicines Prices Review Board were presented as a hallmark of the Federal Government's goals to improve accessibility and affordability of prescription medications. However, the proposed amendments will directly impact only one segment of Canada's prescription drug market – the manufacturers' prices of patented medicines – and may adversely impact other segments, including patient access to optimal treatments.

As proposed, the amendments will introduce concepts of pharmacoeconomics and ability and willingness to pay as factors the PMPRB must consider in determining if a price is excessive. These factors are currently used in Canada by public and private drug plans, who are the actual payers. They negotiate terms and conditions of coverage with manufacturers, including price discounts and rebates related to the volume of expenditure and payer's assessment of value to the drug plan. It is not evident why a duplication of that analysis by the PMPRB will be of benefit. On the contrary, it risks adding another layer of review, delays in patient access and market uncertainty, and has the potential to disrupt the current product listing framework used by public drug plans to maximize the value they receive. It has been suggested that additional savings can be achieved through lower prices. The pCPA is already obtaining savings estimated to be about $1 billion annually. If substantial additional savings are achieved through lower prices for patented drugs, an impact assessment is required to determine the effect on the ability and willingness of manufacturers of innovative drugs to maintain their record of bringing new products to Canada earlier than in many other lead jurisdictions.

Innovative drugs help to save lives and may also achieve savings elsewhere in the health care system. This has been very evident in the life saving therapies for HIV/AIDS, hepatitis C, and numerous cancers. Some of the innovations have been truly breakthrough, while others, particularly in many cancer treatments, have provided incremental improvements which have dramatically changed outcomes for patients over time.

In your remarks on May 16, you emphasized your recognition of the value that truly innovative new therapies may bring and announced a policy review by Health Canada and CADTH to find ways to align their processes to bring such important products to market faster to benefit patients. We applaud this initiative. It will be counterproductive however, if a new pricing regime for these products, on top of the existing CADTH and pCPA frameworks, creates more delays and disincentives to manufacturers to launch new products or those which offer modest yet important advances in Canada.

Life Sciences Innovation & Affordability: Ensuring Policy Congruence

As the Government of Canada contemplates the role for the health and bio-sciences sector in Canada's innovation economy and determines how to support this sector's growth, the impact of the proposed amendments to the *Patented Medicines Regulations* on future innovative medicines must be considered.

Canada's life sciences sector has been highlighted for its growth potential under the federal government's Innovation Agenda, and complementary life sciences strategies have been developed in the provinces, particularly in Quebec and Alberta. The pharmaceutical sector also features prominently in Canada's trade agenda, such as the recently-concluded Canada-European Comprehensive Economic and Trade Agreement (CETA) and the upcoming renegotiation of the North American Free Trade Agreement (NAFTA). The international context

and impact must be considered in the exercise to change Canada's domestic pharmaceutical pricing framework.

Development of medicines is a global process. Across J&J and our counterparts in the innovative biopharma sector, investment decisions in research and development are complex and extremely competitive. Key factors driving those investment decisions are not just the presence of promising science, but also the presence of a marketplace which is open to innovative technologies and demonstrates willingness to recognize the value of innovation through health system adoption of new technologies. This creates opportunities for biopharma to recoup the investment in pharmaceutical innovation – a lengthy and risky process.

A more complex and uncertain pricing environment in Canada will cause global companies investing in innovative new medicines to make business decisions that will directly impact access by Canadian patients to innovative new medicines. This will mean reduced investment in clinical trials in Canada, fewer or delayed launches of new medicines in Canada, less ability to negotiate confidential rebates with public payers and result in fewer medicines available to Canadian patients. Longer term, it 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 access to new medicines. The absence of new therapies or major delays in introduction will also impact Canada's ability to attract clinical trials, due to the absence of relevant comparators on the market.

Despite Canada's strengths in economic performance, including leading the G7 in economic growth for the past decade, and the presence of stable and transparent regulatory frameworks, 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. Our health and innovation policies should be aligned and reflect our aspiration to continue to be a leader and not settle to be in the middle of the pack of the OECD in terms of access to innovative medicines.

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 whole of government lens must be applied to the proposed changes to the PMPRB to ensure that the goals of innovation are congruent with those of prescription drug affordability and strike a balance that maximizes the public good.

Inclusive Solutions Require Inclusive Consultation

To address the challenges of prescription drug affordability while ensuring an innovative economy that enables inclusive growth, a full multi-stakeholder consultative approach needs to be considered. This will create opportunity for innovative and creative solutions to the affordability problem and result in a more inclusive solution for Canadians. Proceeding with a solution that only impacts patented drugs is an incomplete solution that will have consequences for Canadians, their access to treatment and for our health and wealth.

The Johnson & Johnson Family of Companies in Canada is willing to act and sit at the table with you and your provincial and territorial colleagues and all stakeholders in this ecosystem – patients, industry, researchers and insurers – to collaborate and find solutions to these challenges that impact the health and well-being of all Canadians and our economy. Such solutions take courage and leadership to identify common goals and resolve conflicts among

stakeholders to achieve an outcome that fully addresses prescription drug affordability. J&J looks forward to working with you to achieve this outcome.

Sincerely,

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Executive Director, Worldwide Government Affairs & Policy (Canada)
Johnson & Johnson
Chair, Government Affairs Council
Johnson & Johnson Family of Companies in Canada

CC: Hon. Navdeep Bains, Minister of Innovation, Science and Economic Development
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Patented Medicines Regulations Consultations (via email: PMR-Consultations-RMB@hc-sc.gc.ca)