Johnson & Johnson
FAMILY OF COMPANIES IN CANADA

October 31, 2016

Douglas Clark
Executive Director
Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear Mr. Clark:

On behalf of the Johnson & Johnson Family of Companies in Canada (J&J) we are pleased to provide input in response to the Patented Medicine Prices Review Board (PMPRB) Guidelines Modernization Discussion Paper dated June 2016.

Through the ongoing efforts of our five businesses in Canada, J&J is a leader in Canada's health care sector -- researching, developing and manufacturing consumer health and personal care products, breakthrough pharmaceutical medicines, and medical devices. Our enterprise in Canada employs more than 2,500 Canadians and includes:

- **Johnson & Johnson's Consumer Healthcare division,** the leading consumer health and personal care products business in Canada, with offices in Markham, Ontario and a manufacturing plant with global R&D labs in Guelph;
- **LifeScan Canada,** committed to improving the lives of people with diabetes and is located in Burnaby, British Columbia;
- **Janssen,** our biopharmaceuticals company with facilities in Toronto, Ontario;
- **Johnson & Johnson Medical Companies,** marketer and distributor of medical devices with offices in Markham, Ontario; and
- **Vision Care,** a leading eye care products business, also located in Markham, Ontario.

Our vision is to enrich the health and wellness of every Canadian, every day. J&J believes that modern legislation and policy frameworks, evidence-based regulation and timely access to health care products are critical to improving the health and safety of all Canadians. We are committed to working with government and other stakeholders to ensure Canada continues to be a country where innovative high-quality treatments are available to all citizens, with a regulatory, economic and health policy framework that encourages and supports the development and utilization of innovative treatments. We are also committed to continuing to work with governments and other stakeholders to ensure the sustainability of our healthcare system.

J&J is committed to public policies that enable increased competitiveness, advance innovation to improve the health of Canadians and make life-changing and sustainable differences in human health. J&J is the largest and most diversified healthcare company in the world; as such we have important breadth and depth of knowledge and experience to help inform healthcare policy.

PMPRB is responsible for ensuring prices of innovative medicines in Canada are not excessive. PMPRB exercises this role through the assessment and regulation of patented pharmaceutical prices. These assessments may not only include traditional prescription medicines, but also technologies such as medical devices that may contain a drug, over the counter medications and other products developed and marketed by J&J. While the PMPRB most frequently interacts with Janssen Inc., the pharmaceutical company of J&J, some of our other businesses are currently or may in the future have interactions with the PMPRB, including our Johnson & Johnson Consumer Healthcare Division, Johnson & Johnson Medical Companies and VisionCare.

For more than 20 years, the PMPRB has reported that prices for patented medicines have met the objectives set for the program:

- Prices in Canada for patented medicines have been below median international prices; and
- Prices of patented medicines increased by 0.1% in 2015 and have never increased by more than the rate of inflation for over 20 years; and
- The vast majority of prices for patented medicines are compliant with the Guidelines and when they are not, PMPRB has been successful in lowering the price and/or requiring the payment of excessive revenues as permitted under the *Patent Act* (Canada)

Policies of other levels of government and market forces have also contributed to this pricing performance, including HTA assessments, cost containment measures and negotiated contracts.

In view of the significant changes in drug pricing and reimbursement in recent years, we understand the desire of the PMPRB to review its policies to ensure they remain current in the Canada's dynamic healthcare environment. But given the complexity and interconnectedness of the many stakeholders involved in the healthcare system, we believe it is also important to ensure that any policy changes are clearly supported by evidence and that they do not impinge on the responsibilities of other players in the system or have detrimental unintended consequences on our health care system as a whole. Above all, as a statutory administrative tribunal, it is incumbent on the PMPRB to ensure any changes are grounded in the policy and legislated mandate of the PMPRB - to encourage the introduction of new technologies to improve the health of Canadians at prices that are not excessive.

The PMPRB Strategic Plan of 2015 and the more recent Discussion Paper explore potential changes to PMPRB's role in light of the changing reimbursement environment in Canada. It is suggested that the PMRPB move away from assessing 'excessive' price and instead determine 'affordable' price. As described in the Janssen submission to PMPRB, this is not within the legal scope of the *Patent Act* and cannot be changed without debate in Parliament and should not be pursued without a thorough

consideration of the impact on the entire system that impacts the introduction of new technologies in Canada.

As a broad-based health company, we develop and manufacture products that help Canadians live healthy lives across a wide spectrum, from over-the-counter medicines to artificial hips to blood glucose monitoring devices. Therefore, we have a particular focus on ensuring the healthcare system is able to provide optimal healthcare and healthcare products to Canadians. We also feel, as you do, that regulatory resources should be used in a way that focuses on solutions that have a positive impact on the healthcare system, while ensuring that the same solutions do not result in negative or unintended consequences to the larger system.

For example, the current guidelines and regulatory focus are not suitable for all patented drugs, particularly with respect to over-the-counter (OTC) drugs that involve very different product selection processes (direct to consumer) and competitive market dynamics. For the most part, patented OTC products are not reimbursed, yet they are an affordable, out-of-pocket cost paid by almost everyone. OTC drug products are sold in a highly competitive consumer products environment where price is moderated through typical market dynamics.

Even though patented OTCs are currently regulated by PMPRB on a complaints basis only, there is still a considerable amount of administrative burden required to manage these complaints. The OTC market is highly competitive and is characterized by seasonal price movements and ad hoc competitive pricing campaigns. Most products in this market are not patented, and therefore, are not subject to the PMPRB's oversight. The complex PMPRB rules impose not only a regulatory reporting burden on patented OTC products, but also put real constraints on the ability to adjust price quickly, such as offering special discounts or other benefits in response to dynamic market conditions.

Health Canada has proposed that OTC drugs be categorized as self-care products within the Consumer Health Products legislative framework, encompassing OTC drugs, natural health products and cosmetics. Similar to the waiving of PMPRB rules for natural health products we would like to see PMPRB rules waived for self-care products. In the interim, and in consideration of the nature of self-care market dynamics, we think that it would be appropriate to allow full price discount recovery and full inflation adjustment without an annual cap. Similarly, international price comparisons are not appropriate in the highly competitive OTC market.

With that in mind, reducing regulation on patented OTC medicines should not be seen as a quid pro quo for increasing the focus on single source and highly innovative drugs. Any changes affecting the latter group should only be considered in light of clear evidence that they are required and will be effective to achieve their intended purpose. The PMPRB currently applies rigorous regulatory oversight over these products and has been able to achieve high rates of compliance under the current regime. The PMPRB needs to work more collaboratively with all stakeholders to ensure that any changes to the PMPRB Guidelines do not limit access for Canadians to the most innovative healthcare technologies. Access to innovation has been clearly demonstrated to improve patient and population health and reduce

healthcare costs. Healthcare innovation is not simply a line item in a budget, but if offers great value to the system and, most importantly, to patients.

A second area of focus for the PMPRB that has broader implications for the healthcare system is the concept of differential pricing. While the PMPRB identifies a maximum 'non-excessive' price, many payers and customers may pay different prices below this threshold. This is usually due to contracts and agreements negotiated with different customers, such as public payers, private payers, hospitals, clinics, GPOs. The same dynamics are also applicable to OTC drugs. Agreements with different customers, offering different prices based on factors such as a customer's purchasing volume or other conditions of sale are normal practice in a wide variety of industries. In its Discussion Paper, the PMPRB has suggested that using differential pricing strategies is a form of 'excessive' pricing. This is clearly not the case if all customers are paying a price below the PMPRB ceiling. Removal of the ability to negotiate agreements with differential pricing would make it difficult to provide appropriate value to different customers, resulting in higher prices for some.

The PMPRB has stated that it wishes to decrease regulation on those technologies where there is competition. The Discussion Paper recognizes that there is less need for price regulation in more competitive segments of the market. Since confidential contracting and agreements are part of the competitive market dynamics that keep prices in check across the healthcare system, it is unclear how removing the ability to enter into such contracts would help ensure prices are not excessive.

As a major funder of healthcare research and development (R&D) in Canada, J&J is proud to enable new innovations designed to optimize health for Canadians. Our JLABS facility, which opened earlier this year at the MaRS Centre in Toronto, is a leading example of the most up-to-date approaches to health care innovation. A collaboration among J&J, The University of Toronto, MaRS Discovery District, the Government of Ontario and others, the 40,000-square foot facility provides entrepreneurs with access to highly specialized tools and skills building programs to design and develop smart health technologies.

The current focus on short-term cost containment in health raises concerns not only from a health outcomes perspective, but also from the perspective of research funding in Canada. Canadian researchers and innovators in the health technology industry will struggle even more to obtain the necessary investments in Canadian R&D if the value of innovations are not recognized and funded by the health system in Canada. The Prime Minister and the federal Ministry of Innovation, Science and Economic Development (ISED) have set a clear priority on an Innovation Agenda for Canada, including innovation in the life sciences sector. The Finance Minister has a broader focus on economic growth. Together these policies represent a coherent and forward-looking strategy for future economic development in Canada based on technological innovation. The PMPRB needs to collaborate not only with colleagues in the Ministries of Health, but also with the Ministries responsible for Innovation and Finance, both federally and provincially, to ensure that any changes to the pricing of patented medicines in Canada do not hamper the Innovation Agenda and growth objectives.

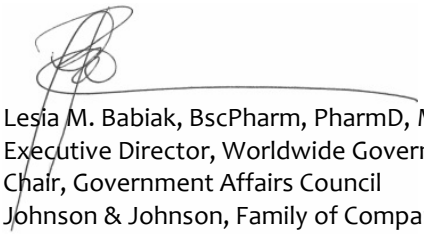
For example, the PMPRB has suggested that it may stop recognizing the value of a product's level of

innovation in its pricing assessments. Such a change would appear to be at odds with the mandate of the PMRPB outlined in the *Patent Act,* which is designed to encourage innovation, and with the federal government's objectives in the Innovation Agenda.

J&J recognizes that managing health budgets is a concern for public and private payers and, in particular, for health ministers across the country and that the PMRPB is seen as one of the levers to help control costs. As such, budget issues should not be looked at in isolation and any possible changes to the PMPRB's mandate or operating policies must be studied carefully, in consultation with the broad range of impacted stakeholders, to ensure that any changes are evidence-based and will not lead to unintended consequences that impact negatively on optimal health care for Canadians.

In conclusion, healthcare quality and innovation in Canada are a singular focus for the companies of Johnson & Johnson. As such, we welcome the opportunity to collaborate with all key players in the healthcare system in order to ensure that any changes in the policy and regulatory environment in Canada result in maintaining and enhancing access to innovative treatments today and for the future, as part of a sustainable healthcare system.

Yours sincerely,



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PMPRB Board