Johnson & Johnson
FAMILY OF COMPANIES IN CANADA

February 14, 2018

Karen Reynolds
Executive Director
Office of Pharmaceuticals Management Strategies
Strategic Policy Branch
Health Canada
10th Floor, Brooke Claxton Building
70 Colombine Driveway, Tunney's Pasture
Ottawa, Ontario K1A 0K9

VIA E-MAIL**:** PMR-Consultations-RMB@canada.ca

Re: Proposed Amendments to the Patented Medicines Regulations

Dear Ms. Reynolds,

The Johnson & Johnson Family of Companies in Canada (J&J) understands and shares the objective of the Minister of Health to improve access to prescription medications, reducing the cost Canadian governments pay and making them for affordable for all Canadians.

However, J&J would like to register its strong objections to the proposed amendments published in the Canada Gazette, Part I on December 2, 2017. It is our recommendation to the Minister of Health to suspend the regulatory amendment process and to engage in an active dialogue and work in partnership with the innovative biopharmaceutical sector to find an alternative solution to achieve these shared goals.

J&J is the leading healthcare company in the world. In Canada, our Family of Companies is a leader in Canada's health sector, researching, developing and manufacturing consumer health and personal care products, breakthrough pharmaceutical medicines and medical devices. We employ 2,100 Canadians at six sites across Canada.

Our vision is to enrich the health and wellness of every Canadian every day. Our pharmaceutical arm, Janssen Inc., is the major supplier of prescription medicines in Canada in an important range of therapeutic areas. Our innovative products save lives, improve health outcomes and quality of life for patients and help to lower costs in other parts of the health care system.

J&J also plays an important role in the life sciences ecosystem. J&J has invested more than $1 billion in Canada's life sciences ecosystem, since the successful conclusion of the Canada-

European Union Comprehensive and Economic Trade Agreement in 2014. Major investments, such as our groundbreaking JLABS @ Toronto facility, a world-class life sciences incubator to advance innovation at emerging Canadian companies, provide concrete evidence of our support for the Federal Government's Innovation Agenda.

However, the vast majority of these investments are not entitled to be considered as R&D investments under current criteria. The Regulatory Impact Analysis Statement (RIAS) for this proposal does a disservice to our company and industry by using outdated and incomplete data to describe our industry's record on research investments in Canada; as but one example, our investment in JLABS is not included.

J&J fully endorses the submissions by Janssen and our industry associations Innovative Medicines Canada and BIOTECanada. We would also draw certain additional considerations and perspectives to the government's attention.

The Need for Reform

The statements from the Federal Government and RIAS in support of the proposed regulations are based on incomplete evidence and provide inadequate and faulty analysis. Without some common understanding of the nature of the "problem" to be addressed, it will be impossible to obtain consensus on appropriate policy options.

The most glaring examples of the gaps in evidence are the absence of references and even recognition of the key metrics of patented medicine price trends and prescription drug spending as reported by the PMPRB itself and the Canadian Institute for Health Information (CIHI). Despite statements that drug prices and spending are up, the evidence suggests otherwise:

- Patented drug prices have not increased by more than the CPI in 25 years; in fact, they declined in 2016.[1]

- Canadian prices ranked fourth in relation to the seven comparator countries and 25% below the median of the foreign prices, the lowest level ever reported.[2]

- The RIAS states that drug spending now accounts for a larger share of total health spending than 49 years ago; while this is true, it is highly misleading since drug spending as a share of total health spending has been stable between 16.0% and 16.8% for the past 15 years and was forecast at 16.4% in 2017.[3]

Instead, the RIAS introduces comparisons with drug prices in all 35 OECD countries and claims that Canadian prices were 22% above the OECD median. We cannot find any analysis the government has released or cited to support a new policy objective of the OECD median in drug prices or any other component of healthcare.

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[1] Patented Medicine Prices Review Board, Annual Report 2016, November 2017. Available from: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1334
[2] Ibid.
[3] Canadian Institutes of Health Research, National Health Expenditure Trends, 1975-2017, November 2017. Available from: https://www.cihi.ca/sites/default/files/document/nhex2017-trends-report-en.pdf

J&J recognizes the concerns of governments and insurers about the future challenges of ensuring appropriate mechanisms in our healthcare system to manage the allocation of resources around high technology breakthroughs such as CAR-T. J&J shares Janssen's view that any changes to the patented medicines regulations need to start with the following first principles:

- Optimal healthcare for all Canadians
- Canada needs to remain a country where innovative medicines are available to all citizens
- It is befitting a country with an advanced economy and global stature of Canada to promote and maintain economic and health regulations that encourage and support the development of innovative treatments

We would like to engage government on these issues, but that conversation should start with an evidence-based assessment of the current situation.

The Proposed Introduction of Pharmacoeconomics as a Determinant of Excessive Pricing under the *Patent Act*

J&J endorses the views of other stakeholders that pharmacoeconomics is inappropriate to the mandate of the PMPRB:

- Pharmacoeconomics is used to establish ranges of cost-effectiveness based on various assumptions reflecting the perspective of the user; no jurisdiction in the world uses a fixed cost-per-QALY threshold to establish a national price.
- Instead, it is used to inform negotiations between payers and manufacturers on the terms and conditions of coverage. Canada's public drug plans rely heavily on pharmacoeconomic analysis in this way. The pharmacoeconomic models used by CADTH and INESSS are designed to assess value to the public healthcare system, not to determine a non-excessive price for all consumers in Canada. The mandate of PMRPB is to review potential excessive pricing, not to determine one national price for all payers.
- The PMPRB concedes that it would take one or two years or more to establish a price using this factor; therefore it cannot be used to establish a clear bright line that allows patentees to know the allowable price at the time of launch. The uncertainty and variability in analysis are certain to increase legal challenges.

In 2013, Health Canada commissioned a report, *Investigation and Analysis of Options to Enhance Canada's Patented Medicine Price Ceiling Regulatory Regime*, that concluded that value-based assessment using pharmacoeconomics was inappropriate for the PMPRB's

statutory mandate.[4] Health Canada has not acknowledged that report in the RIAS nor has it provided any facts or analysis to challenge its conclusions.

Canada's Innovation Agenda

Perhaps the greatest weakness of this policy proposal is the failure to take into account the important linkages with other federal and provincial government programs. The RIAS neglects to consider how reporting of confidential third-party rebates might impact the successful F/P/T pan-Canadian Pharmaceutical Alliance and that it will reduce the value of international price comparisons. While it purports to address "affordability," it provides only superficial and incomplete analysis of the impact on the Minister's objectives of "accessibility" and "appropriate use" of pharmaceuticals.

The proposed regulations fail to make any linkages to the federal government's Innovation Agenda and provincial innovation policies such the Quebec Life Sciences Strategy, which has seen the provincial government invest $205 million over five years and set ambitious investment targets.

The impact to industry is underestimated in the proposal's RIAS and in its Cost-Benefit Analysis. While it is assumed that innovative pharmaceutical industry will continue 'business as usual,' this is a false assumption. In fact, the proposal is estimated to reduce industry revenues by $26.1 billion over 10 years and create lengthy pricing uncertainty which will have major implications on industry investment in Canada, employment and access to new breakthrough treatments.[5] The loss of these investments will not only impact our companies directly, but it will also endanger the potential and growth of Canada's life sciences sector, a key sector of Canada's Growth agenda.

Recommendation

J&J recognizes that governments in Canada understand the need to prepare for future developments in health technology and the objective of the Minister to improve access to prescription medications, reducing the cost Canadian governments pay and making them for affordable for all Canadians. We are deeply concerned the proposed regulatory changes will not result in the stated goals of improved affordability, access to, and appropriate prescribing of innovative medicines and will create unintended and negative consequences for Canadians and crippling consequences for Canada's life sciences ecosystem.

We strongly encourage the government to suspend the current proposals and start a new dialogue with stakeholders to assess the issues, identify options and establish priorities. We hope that future dialogue with stakeholder is meaningful and provides policy options which

[4] Husereau D, Jacobs P. Investigation and analysis of options to enhance Canada's patented medicine price ceiling regulatory regime. Edmonton AB: Institute of Health Economics, 2013. Available from: https://www.ihe.ca/advanced-search/investigation-and-analysis-of-options-to-enhance-canada-rsquo-s-patented-medicine-price-ceiling-regulatory-regime

[5] PDCI Market Access. Proposed Amendments to the Patented Medicines Regulations: A Critical Appraisal of the Cost-Benefit Analysis. January 2018. Available from: http://www.pdci.ca/wp-content/uploads/2018/01/20180129_PDCI-Critical-Assessment-PM-Regs-Amendments_Report-Final.pdf

balance the federal government's objectives with a vibrant, thriving innovative life sciences ecosystem in Canada.

Please be assured that J&J is willing and anxious to participate in this dialogue with constructive solutions.

I look forward to hearing from you in the near future.

Sincerely,

Dr. Lesia Babiak, BScPharm, PharmD, MBA
Executive Director, Worldwide Government Affairs & Policy (Canada)
Chair, Government Affairs Council
Johnson & Johnson Family of Companies in Canada

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