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VIA ONLINE SUBMISSION PORTAL

House of Commons Standing Committee on Health
Parliament of Canada
Ottawa, ON K1A 0A6

Dear Members of the House of Commons Standing Committee on Health,

On behalf of the Johnson & Johnson Family of Companies in Canada (J&J) we would like to provide input to the committee's study on the imminent coming into force of reforms to the Patented Medicines Prices Review Board (PMPRB) regime. We would ask the Committee to consider, in its recommendations, the appropriateness of the January 1, 2021 implementation, given the impact of the pandemic and the negative effects PMPRB reform will have on patient access, research, and investment.

- J&J understands the government's objective of addressing the affordability of medicines. That is why we joined our trade association with an alternative proposal.
- We are extremely concerned that the PMPRB reforms create a policy regime that is incompatible with other countries.
    - Our concern is not solely the potential impact on drug prices. The planned PMPRB reform is a wholesale redevelopment of the system that will establish unclear, unprecedented and untested approaches to price regulation that will create significant barriers to the launch of innovative drug therapies in Canada.
- J&J believes there is an opportunity to find constructive, alternative approaches to regulations and guidelines that will meet the government's objectives on affordability while continuing to foster a strong health and life sciences sector.
- Innovative Medicines Canada has laid out the innovative industry's core issues with the reforms, with which we concur. We worry that the following downstream effects of this reform will occur:
    - The focus on pricing, net of rebates to third parties, ("net price") will leave Canada "on an island" internationally. No other jurisdiction regulates net price in this manner.
    - As many other countries reference the Canadian price when pricing medicines, a significant reduction to Canadian prices would have global effects. This could delay launches in Canada.
    - The new rules (particularly the application of pharmacoeconomics to set prices) will discourage new medicines from coming to Canada as they entail ongoing and significant pricing uncertainty. We are already seeing fewer product launches in Canada, with a big decline beginning in 2018 when the direction of the PMPRB changes was emerging.
    - We also expect that clinical research investment will go elsewhere, and as such, the overall Canadian life sciences research environment will weaken.

- Industry-wide, we are already seeing deferred or delayed product launches. This is impacting Canadian patients in key areas such as oncology and cystic fibrosis.
    - Product launches are being delayed or cancelled – including Vertex's Trikafta® and Roche's Tencentriq®.[1,2]
    - We have seen a notable reduction in new regulatory filings to Health Canada since August 2019 compared with prior years – the earliest of indicators. [3]
    - Many products that have approval are not being launched in Canada. Nearly half of recently approved products by Health Canada still have not been launched within six months – far outside of the normal trends we would expect to see.[4]
- These impacts will be magnified for Canadian patients and the quality of their healthcare:
    - Fewer products coming to Canada will deprive patients of medically necessary treatments.
    - Fewer clinical trials will prevent patients from accessing cutting-edge innovation that may yield substantial benefits for them. Once the PMPRB regulations were finalized in August 2019, new clinical trial initiations in Canada fell by a substantial 48% year-over-year.[5] While this is an early indicator, taken together with other observed changes, it is of serious concern.
- As for Janssen Canada, the PMPRB reform will force J&J to reconsider launch decisions.
    - **Until further notice and directly linked to the PMPRB changes, J&J and Janssen Canada have placed the following under active review**:
        - All future Canadian product launches;
        - Canada's status as an early global launch jurisdiction;
        - Any new research and development investments in Canada (a departure from the $1B+ committed since 2014);
        - Continued support of our JLABs facility in Toronto;
        - All Janssen Canada clinical trials; and
        - Janssen Canada engagement of Canadian agencies such as CADTH in providing early scientific advice for global development plans.
- Industry-wide, the cost of the PMPRB reforms could exceed $41.8 billion in lost revenues.[6] That cost is significant and material to future business decisions.
    - A recent analysis from the Université de Montréal found that the new basket of international comparators, the PMPRB11, **could reduce prices for existing drugs by 28.4%,** to say nothing of new drugs coming down the pipeline.[7]

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[1] Canadian Organization for Rare Disorders, Submission to PMPRB on the revised Draft Guidelines, https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/submission-received/june2020/June%202020%20submission_Canadian%20Organization%20for%20Rare%20Disorders%20(CORD)_EN.pdf

[2] Allison Martell, Exclusive: Canadian regulator considers changes to new drug pricing plan, https://www.reuters.com/article/us-canada-pharmaceuticals-exclusive-idUSKBN20E2LI

[3] Nigel Rawson, Fewer New Drug Approvals in Canada: Early Indication of Unintended Consequences from New PMPRB Regs?, https://www.canadianhealthpolicy.com/products/fewer-new-drug-approvals-in-canada--early-indication-of-unintended-consequences-from-new-pmprb-regs-.html.

[4] Life Sciences Ontario, New Medicine Launches: Canada in a Global Context, https://lifesciencesontario.ca/wp-content/uploads/2020/06/EN_LSO_Global-Launch-Benchmarking_Webinar-June22-20_Final.pdf

[5] Innovative Medicines Canada and Life Sciences Ontario, EARLY SIGNS OF NEGATIVE IMPACTS FOR PATIENTS OF HEALTH CANADA PHARMACEUTICAL PRICING REFORMS, http://innovativemedicines.ca/wp-content/uploads/2020/06/20200630-CADTH-EarlySigns-FINAL.pdf

[6] PDCI, Impact Analysis of the Draft PMPRB Excessive Price Guidelines, https://www.pdci.ca/pdci-analysis-estimates-impact-of-pmprb-draft-guidelines-to-be-up-to-41-8-billion/

[7] Chloé Langevin, Impact of Patented Medicine Prices Review Board New Reference Countries on Drug Prices in Canada: A Comparison of Current and Anticipated List Prices for Top Drugs in the Country, https://virtualsymposium.cadth.ca/2020/07/27/impact-of-patented-medicine-prices-review-board-new-reference-countries-on-drug-prices-in-canada-a-comparison-of-current-and-anticipated-list-prices-for-top-drugs-in-the-country/

    - **There have also been early and negative impacts on sector employment**. At least one major company has reduced its Canadian headcount by 30%.[8]
- Two legal challenges are currently underway:
    - In the first, the Federal Court struck down a key section of the new regulations – the obligation to report net prices. Despite this decision, the PMPRB still intends to consider net prices in hearings.
    - Janssen is a party to a second action in the Quebec Superior Court which challenges PMPRB reform as being unconstitutional.[9] The remaining arguments in this case are scheduled to be heard in November.
- Imposing these drastic changes, despite the serious concerns raised by industry, patient groups and clinicians – amid a pandemic, degrade the investment climate in Canada. The value of new medicines to save lives and improve the health of our citizens has never been more evident than in the time of this global health crisis.
    - J&J is currently actively recruiting for our stage III COVID-19 vaccine trial and undertaking major manufacturing efforts at risk.
    - We were pleased to have reached an agreement in principle with the Canadian Government earlier this year to supply up to 38 million doses of our vaccine candidate, should it be proven safe and effective. We are providing this vaccine on a not-for-profit basis during the pandemic.
    - This work will help us move out of this pandemic and help us to address future pandemics.
    - The new PMPRB regime weakens our ability to respond to future health crises and diminishes Canada's engagement and contribution to the efforts of our industry. There is an impending risk that with the implementation of this policy, Canada will be left behind.

Never has the health of our economy been more dependent on the hard work, innovation, and ingenuity of the life sciences industry as it is today. Given the scale and scope of unaddressed concerns from stakeholders, J&J calls on the Health Committee to recommend that the Canadian Government **defer implementing the new PMPRB regime** until:

- The validity of the reforms has been settled in the courts;
- Alternatives have been explored through active dialogue with senior industry and government leaders; and
- Harmful implications have been managed appropriately.

Thank you,

Jorge Bartolome
President, Janssen Canada

cc: Dr. Lesia M. Babiak, Executive Director, World-Wide Government Affairs & Policy (Canada)

[8] Pharmaceutical Online, NJ Plant To Lose Merck Jobs In Company Reorganization, https://www.pharmaceuticalonline.com/doc/nj-plant-to-lose-merck-jobs-in-company-reorga-0001

[9] J&J company Janssen Canada is a litigant in an ongoing suit in Quebec Superior Court challenging the constitutional validity of the PMPRB. Nothing in this submission is an admission in or derogation from Janssen's position as expressed in the above proceeding.