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Attention: Standing Committee on Finance
Hon. Wayne Easter, Chair

RE: The Standing Committee on Finance's pre-budget consultations in advance of the 2022 budget

Dear Mr. Easter:

This submission is in response to the Standing Committee on Finance's pre-budget consultations in advance of the 2022 budget. In conjunction with this submission, AbbVie is supportive of the positions expressed by Innovative Medicines Canada (IMC) and BIOTECanada (BTC), two industry associations of which AbbVie is a member.

AbbVie is an innovation-driven, patient-focused specialty biopharmaceutical company. Our mission is to discover and deliver, to Canadians, innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on Canadians' lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health, and gastroenterology. AbbVie is presently the 2nd largest biopharmaceutical company operating in Canada, and with the recent acquisition of Allergan, we are proud to employ in Canada nearly 1,000 employees. AbbVie has Canadian headquarters in Markham, Ontario, and Montreal, Quebec.

AbbVie was pleased to make note of Budget 2021's focus on "Strengthening Canada's Bio-manufacturing and Life Sciences Sector,"[1] and we provide the following recommendations to further support this objective through Budget 2022:

- Recommendation 1: Do not pursue the planned January 1, 2022 Regulatory amendments pertaining to the Patented Medicine Prices Review Board (PMPRB); rather, protect existing medicines from drastic price measures because these measures will negatively impact the life sciences sector in Canada, and AbbVie in particular, and Canadians' access to innovative medicines.

- Recommendation 2: Partner with the life sciences sector on a Life Sciences Strategy for Canada that includes a reliable and predictable regulatory system that values and rewards innovation.

Recommendation 1: Do not pursue the planned January 1, 2022, changes to the Patented Medicine Prices Review Board (PMPRB) because they will negatively impact the life sciences sector in Canada and Canadians' access to innovative medicines

Budget 2021 stated an important objective—that "Growing Canada's life sciences and bio-manufacturing sector is a priority that goes beyond responding to COVID-19. This is a growing sector that supports thousands of good, middle class jobs."[1] Meanwhile, contrary to this worthy objective, Health Canada continues to plan for the January 1, 2022, coming-into-force of the *Regulations Amending the Patented Medicines Regulations*, which will have the opposite effect of strengthening this sector which has proven to be so vital to Canadians.

[1] https://www.budget.gc.ca/2021/report-rapport/toc-tdm-en.html

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On multiple occasions, and in AbbVie's Federal Pre-Budget Consultation Submission dated February 19, 2021,[2] we have identified that the forthcoming amendments to the PMPRB Regulations, now planned for January 1, 2022, will pose serious challenges to our ability to introduce new innovative medicines to Canadians and will compromise our current investments in the Canadian life sciences sector. Emerging research evinces similar concerns:

- For example, on February 4, 2021, an article in the *Canadian Health Policy Journal* titled "Clinical Trials in Canada: Worrying Signs that Uncertainty Regarding PMPRB Changes will Impact Research Investment"[3] points to a 26% decrease in the number of phase III/IV clinical trials in 2020 compared to 2015-2019. The author notes that "When drug developers perform fewer clinical trials in Canada, investment in research is reduced and employment opportunities are lost. It can also be a sign that manufacturers do not intend to bring new medicines here." As the title and the text of the article suggest, this lack of intention to launch in Canada is attributable to changes to the PMPRB.
- Additionally, research published on January 21, 2021, by Life Sciences Ontario and Research Etc.[4] reported on a survey of 43 senior pharmaceutical executives: 35% responded that they have already delayed bringing new treatments to Canada; 96% (*i.e.*, 41 out of 43 senior pharmaceutical executives) anticipate that the new PMPRB Regulations will drive decisions to delay or not bring new treatments to Canada; 90% say the reform will reduce research, clinical trials, and innovation.

Furthermore, AbbVie has serious concerns regarding the PMPRB's latest unacceptable proposal of July 15, 2021, to reduce the prices of existing medicines (known as "grandfathered medicines") and their line extensions as early as July 2022 by adopting a new transitory price test.[5] As noted in the Canada Gazette, Part II, on June 10, 2020, patented medicines sold in Canada prior to August 21, 2019, were exempted from the new regulatory pricing factors and their associated reporting obligations "to respond to industry concerns and provide greater stability for existing medicines" and ***"to provide a degree of continuity for existing medicines."***[6] Continuity means exactly that: continuity of the PMPRB's past practice of controlling excessive pricing of introduced patented medicines. Continuity of past practice for existing patented medicines results in predictability and provides some certainty to manufacturers regarding the pricing of existing medicines. Further, there was an expectation in Canada Gazette, Part II, that grandfathered medicines would not suffer a reduction in prices: "Not all medicines will see a reduction in prices, as most existing products are still expected to be priced below the non-excessive price ceilings, even after the coming-into-force of these Amendments."

However, the newly proposed amendment from the PMPRB conflicts entirely with this principle of continuity, which is so critical to the viability of AbbVie's business in Canada and its patients' continued access to existing medicines. In other words, the combined impact of having to significantly reduce the prices of existing medicines, in addition to highly uncertain pricing Guidelines for new medicines, means that AbbVie, and manufacturers like it, will be faced with extremely difficult decisions regarding the availability of existing and new medicines for Canadians, in addition to ongoing and future life sciences investments.

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[2] AbbVie submission to Pre-Budget Consultations in Advance of the 2021 Budget. February 19, 2021.
[3] https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada--worrying-signs-that-pmprb-changes-will-impact-research-investment.html
[4] https://lifesciencesontario.ca/new-survey-data-federal-drug-pricing-regulations-are-already-stopping-what-canadians-wantaccess-to-new-medicines-as-soon-as-possible/
[5] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-references-comparator-countries.html
[6] Canada Gazette, Part II, Volume 154, Number 12: Regulations Amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements): SOR/2020-126. https://gazette.gc.ca/rp-pr/p2/2020/2020-06-10/html/sor-dors126-eng.html

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The PMPRB's latest proposal purports to affect substantive rights on a retroactive basis by creating a new transitory price test. Canada Gazette, Part II, on June 10, 2020 created a class of "grandfathered" patented medicines and an approach to the pricing of such medicines, to ensure that substantive rights of manufacturers selling such medicines would not be affected on a retroactive basis. Instead, the pricing of such grandfathered medicines appears now to be proposed to be regulated on an unjustifiable retrospective basis. Furthermore, the PMPRB is purporting to amend the law through the Guidelines (and the proposed revisions to the Guidelines) contrary to the most recent decision of the Federal Court of Appeal in *Alexion.* The PMPRB has no power to amend the law (s. 85 of the Patent Act) through the Guidelines. Yet that is exactly what the PMPRB's latest proposal is purporting to do.

The newly proposed amendment of the PMPRB, to move from the HIP of the PMPRB11 to the MIP of the PMPRB7 for existing medicines, is arbitrary if its only purpose was to reduce prices. If the Board wanted to truly protect grandfathered medicines, it would provide that the transitory pricing provision should be pegged to the lower of the NEAP or that price which is he higher of the MIP of PMPRB7 and the HIP of PMPRB11. There will be instances where the MIP of the PMPRB7 will be significantly less than the HIP of the PMPRB11, with the result that this transitory provision is aimed at price control, rather than targeted at abusive pricing, which the Federal Court of Appeal has recently affirmed as being the PMPRB's mandate: see *Alexion Pharmaceuticals v Canada (Attorney General)*, 2021 FCA 157.

Legality and justifiability aside, given the ongoing litigation challenging the PMPRB Regulations, to proceed with these changes, in whole or in part while litigation is ongoing, exacerbates the significant uncertainty for life sciences companies. In the face of this uncertainty, life sciences companies may be forced to take unfortunate and difficult steps that will adversely impact Canadian patients, including AbbVie's, continued access to existing and new medicines.

Recommendation 2: Partner with the life sciences sector on a Life Sciences Strategy for Canada that includes a reliable and predictable regulatory system that values and rewards innovation

In March 2021, Innovation, Science and Economic Development Canada (ISED) and Health Canada (HC) co-launched their consultation titled: "Considering the Creation of New Biomanufacturing Capacity for Canada". In July 2021, they released their "What We Heard" report, identifying that the federal government can play a role by "considering policies that create corporate incentives and foster a competitive and predictable intellectual property regime, and ensuring a responsive and enabling regulatory system that facilitates the uptake and adoption of innovation in Canada."

The currently planned changes to the PMPRB will have the opposite effect of fostering a competitive and predictable intellectual property regime and ensuring a regulatory system that facilitates the uptake and adoption of innovation. First, the application of the economic factors entails that the price of a new, more effective and less costly medicine replacing an existing therapy would be penalized despite not creating any additional expenditure by the payer – i.e. the more effective medicine must be priced lower than the medicine that it replaces, effectively penalizing true innovation. Second, there will remain a high level of unpredictability in the long-term compliance status of launched medicines. This is because the net price ceilings calculated ("maximum rebated price" or MRP) are relying on third-party health technology assessment (HTA) that will not be known until many months after a first sale occurs. Additionally, should an investigation be triggered, PMPRB Staff maintain that they would no longer be bound by Guidelines and may therefore use any and all price tests deemed relevant; reducing certainty, allowing for inconsistencies, and reducing accountability and transparency in decision-making.

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AbbVie saw the latest six-month delay to the PMPRB Regulatory changes as an opportunity to engage with the government to find a solution that meets the government's important public policy objectives, without undermining Canadians' access to new medicines, or driving away much-needed investment in our health and life sciences sector. AbbVie was then further encouraged by the government's new Biomanufacturing and Life Sciences Strategy, which aims to "enable innovation by ensuring world class regulation."[7] Unfortunately, the latest PMPRB Consultation sends a clear signal that PMPRB has little or no interest in effectively delaying the implementation of their new Guidelines or taking that time to engage in any open dialogue with industry. PMPRB seems to remain solely focused on decreasing the prices of existing (grandfathered) medicines, without any consideration for the collateral impact it may have on Canada's life sciences sector.

As stated above, the Federal Court of Appeal has very recently, in the *Alexion* case, issued a stern rebuke to the PMPRB about pursuing a general mandate of price control. AbbVie maintains that enabling an efficient and predictable regulatory system, based on patent abuse and not price control, will not only improve patient outcomes by accelerative access to innovative new medicines, but it will also provide the much-needed encouragement and stability for industry investment.

In conclusion

AbbVie appreciates the opportunity to be engaged in consultations by the Standing Committee on Finance in advance of the 2022 budget. As it is our mission is to discover and deliver innovative medicines for the benefit of Canadians, we have serious concerns that forthcoming changes to the PMPRB Regulations and Guidelines will compromise our ability to do so. We therefore value the Standing Committee on Finance reinforcing the need for the government to rectify these concerns through Budget 2022, and we look forward to engaging with Members of this Committee on these critical matters in the coming months.

Sincerely,

Tracey Ramsay
Vice-President and General Manager
AbbVie Canada

[7] Canada's Biomanufacturing and Life Sciences Strategy. https://www.ic.gc.ca/eic/site/151.nsf/eng/00019.html

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