abbvie

August 31, 2021

SUBMISSION FILED VIA PMPRB CONSULTATIONS INBOX: pmprb.consultations.cepmb@pmprb-cepmb.gc.ca

Attention: Patented Medicine Prices Review Board
Dr. Mitchell Levine, Chairperson of the Board

RE: Notice and Comment - On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions (July 15, 2021)

Dear Dr. Levine:

This submission is in response to the PMPRB's Notice and Comment - *On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions.* 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 innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's 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 nearly 1,000 employees. AbbVie has Canadian headquarters in Markham, Ontario, and Montreal, Quebec.

Proposed price test for grandfathered medicines is inconsistent with stated intentions of the government

AbbVie has serious concerns regarding the PMPRB's latest proposal set out in the Notice and Comment of July 15, 2021. If implemented, the proposal would erode the prices of existing medicines (known as "grandfathered medicines") and their line extensions as early as July 2022 through the adoption of a new transitory price test.[1]

When the amendments to the Patented Medicines Regulation were published in the Canada Gazette, Part II on August 21, 2019 it was clearly stated that medicines sold in Canada prior to August 21, 2019 were exempted from the new regulatory pricing factors and their associated reporting obligations. These medicines were to be exempted ***"to respond to industry concerns and provide greater stability for existing medicines".***[2] Further, there was a clear expectation that grandfathered medicines—i.e., those that are not considered to be priced excessively under the current Regulations—would not be subject to any reduction in prices under the new framework: "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."[2] The

[1] Notice and Comment - On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions. July 15, 2021. https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-references-comparator-countries.html
[2] Canada Gazette, Part II, Volume 153, Number 17: Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements): SOR/2019-298. https://www.gazette.gc.ca/rp-pr/p2/2019/2019-08-21/html/sor-dors298-eng.html

Corporation AbbVie / AbbVie Corporation
C.P. / P.O. Box 120, Pointe-Claire / Dorval
Pointe-Claire (QC) H9R 4N5

Tél. / Tel.: 514-906-9700
Téléc. / Fax: 514-906-9701
www.abbvie.ca

exemption for grandfathered medicines was restated on June 10, 2020, in the Canada Gazette, Part II, noting this was ***"to provide a degree of continuity for existing medicines".***[3]

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. Certainty is critical to the viability of AbbVie's business in Canada and its patients' continued access to existing medicines. The proposed price test described in the Notice and Comment conflicts entirely with this principle of continuity. The proposed test would require a reduction in price for medicines that are currently being sold at non-excessive prices. The implementation of this new, proposed excessive price test would arbitrarily take what is now a compliant price and deem it to be non-compliant. There is no justification for this proposal which is completely at odds with the government's stated intention of ensuring stability and predictability for currently marketed medicines. The combined impact of having to significantly reduce the prices of existing medicines, in addition to the considerable uncertainty now arising as to how other price tests under the Guidelines will be applied 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 in Canada.

Proposed price test is arbitrary, unjustified and not supported by law

The Notice and Comment purports to affect substantive rights of patentees on a retroactive basis by creating a new transitory price test. Per Canada Gazette, Part II, the new Patented Medicines Regulations created a class of "grandfathered" patented medicines and an approach to the pricing of grandfathered medicines, to ensure that the substantive rights of manufacturers selling such medicines would not be affected on a retroactive basis. If the price test of the Notice and Comment is implemented, the pricing of such grandfathered medicines would be regulated on an unjustifiable retrospective basis.

What is equally unjustifiable is that the PMPRB is seeking to amend the law through proposed changes to the Guidelines contrary to the most recent decision of the Federal Court of Appeal in *Alexion*[4]. The FCA clearly stated that 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 proposed price test of the Notice and Comment to move from the HIP of the PMPRB11 to the MIP of the PMPRB7 for existing medicines, is arbitrary as its only purpose and effect are to reduce the prices of grandfathered medicines. If the Notice and Comment is implemented, there will be instances where the MIP of the PMPRB7 will be significantly less than the HIP of the PMPRB11 for an existing medicine. The result of this transitory provision would be to reduce the prices of medicines that are not currently being sold at excessive prices in Canada. This is price control—arbitrary price control—rather than a test that is targeted at excessive pricing. The Federal Court of Appeal recently held that the PMPRB's mandate is only to target abuses in the pricing of medicines: see *Alexion Pharmaceuticals Inc. v Canada (Attorney General)*, 2021 FCA 157.

To avoid a legal challenge, and to respect the expectation of continuity promised by the government, the transitory pricing provision should be pegged to the lower of the NEAP or that price which is the higher of the MIP of PMPRB7 and the HIP of PMPRB11.

[3] 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

[4] Alexion Pharmaceuticals v. Canada (Attorney General), 2021 FCA 157

Corporation AbbVie / AbbVie Corporation
C.P. / P.O. Box 120, Pointe-Claire / Dorval
Pointe-Claire (QC) H9R 4N5

Tél. / Tel.: 514-906-9700
Téléc. / Fax: 514-906-9701
www.abbvie.ca

Legality and justifiability aside, given the ongoing litigation challenging the Patented Medicines Regulations, for the PMPRB to proceed with these changes, in whole or in part while litigation is ongoing, exacerbates the significant uncertainty for life sciences companies. Innovative life sciences companies, including AbbVie, are able to make long-term investments in pharmaceutical innovation based on sound business planning and assumptions in a stable business environment. Our ability to do so in the face of this uncertainty is significantly at risk.

Rationale for the transitory price test is not in good faith

On June 29th, 2021, Health Canada communicated to stakeholders that the coming-into-force date of the Amendments to the Patented Medicines Regulations would be delayed by an additional six months to January 1st, 2022, as a result of the COVID-19 pandemic continuing to pose challenges. Shortly thereafter, in the Notice and Comment the PMPRB states that the proposed consequential changes to the new Guidelines are believed to be an appropriate response to the most recent six-month extension in the coming-into-force date of the Regulations. If that were truly the case, it would be reasonable to assume that the PMPRB would adhere to its previous confirmation that "the MLP for grandfathered medicines will be assessed after two filing periods, as was originally provided for in the new Guidelines".[5] Instead, on August 6, 2021, the PMPRB confirmed: "the operative date for assessing compliance for Grandfathered, Line Extension and Gap medicines with the MLP will remain July 1, 2022"[6] – implying that the MLP for grandfathered medicines will be assessed after only one filing period.

It is also important to note that in the Canada Gazette, Part II, on July 7th, 2021, Health Canada stated that irrespective of the latest six-month delay, it still anticipates that most of the intended savings resulting from the new Regulations will continue to occur as originally estimated[7] and that any such delays would impact "gap" and "new medicines" only (i.e., not grandfathered medicines). The Notice and Comment is very concerning in this light. The PMPRB is citing a COVID-caused delay as the rationale for proposing inappropriate changes to the price test for grandfathered medicines, which to date have been exempted from the new measures as noted above. AbbVie therefore considers the proposal of the Notice and Comment to not be in good faith.

In summary:

AbbVie sees the additional six-month delay in implementation of the Regulations as an opportunity to continue to exchange with PMRPB and Health Canada on finding an appropriate solution that meets the government's important public policy objectives. This includes growing a strong, competitive life sciences sector that enables innovation by ensuring world class regulation.[8] While AbbVie always appreciates the opportunity for consultation, we are gravely concerned by this current Notice and Comment, and we maintain that the PMPRB regulatory changes will have significant unintended negative consequences on patient access to the newest medicines and treatments, while also diverting R&D and investment away from Canada's life sciences sector. A suspension in the PMPRB's regulatory changes and accordingly, of the proposed update to

[5] Decision resulting from the consultation on the definition of Gap medicines and the timeline for compliance. April 16, 2021. https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-definition-gap/decision-definition-gap-medicines.html

[6] Frequently Asked Questions re. Notice and Comment: On the change to the definition of Gap medicines, the references to comparator countries and the international price tests for Grandfathered medicines and their line extensions. August 6, 2021. https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-references-comparator-countries/frequently-asked-questions.html

[7] Canada Gazette, Part II, Volume 155, Number 14: Regulations amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), No. 3: SOR/2021-162. https://gazette.gc.ca/rp-pr/p2/2021/2021-07-07/html/sor-dors162-eng.html

[8] Biomanufacturing and Life Sciences Strategy. July 28, 2021. https://www.canada.ca/en/innovation-science-economic-development/news/2021/07/the-government-of-canada-announces-biomanufacturing-and-life-sciences-strategy.html

Corporation AbbVie / AbbVie Corporation
C.P. / P.O. Box 120, Pointe-Claire / Dorval
Pointe-Claire (QC) H9R 4N5

Tél. / Tel.: 514-906-9700
Téléc. / Fax: 514-906-9701
www.abbvie.ca

the Guidelines, would provide the appropriate time and process to develop a comprehensive strategy to build a thriving life sciences sector in Canada.

We look forward to future opportunities to provide feedback to the PMPRB and will continue to engage in future consultation processes.

Sincerely,

Tracey Ramsay
Vice-President and General Manager
AbbVie Canada

Corporation AbbVie / AbbVie Corporation
C.P. / P.O. Box 120, Pointe-Claire / Dorval
Pointe-Claire (QC) H9R 4N5

Tél. / Tel.: 514-906-9700
Téléc. / Fax: 514-906-9701
www.abbvie.ca