

August 31, 2021

Patented Medicine Prices Review Board  
Box L40  
Standard Life Centre  
333 Laurier Avenue West, Suite 1400  
Ottawa, Ontario K1P 1C1

To whom it may concern,

Thank you for the opportunity to provide feedback regarding the PMPRB's proposed changes to the PMPRB Guidelines in relation to the definition of Gap medicines, the references to comparator countries, and the international price tests for Grandfathered medicines and their line extensions.

The impact of these changes on patentees stands in direct opposition to the Federal government's communicated intent to provide patentees with additional time to prepare for the implementation of the pricing regime that was to be implemented on July 1, 2021. Gilead is aligned and supports the submissions from Innovative Medicines Canada and BIOTECanada.

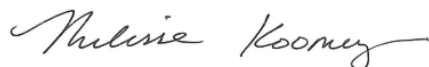
In addition, we agree with our industry colleagues that the proposed changes to the Guidelines concerning the introduction of new MLP calculations for Grandfathered medicines and their line extensions, and the redefinition of the comparator countries, are inappropriate and not aligned with the Federal government's objectives.

To avoid adverse impacts and support the Federal government's position, we urge the PMPRB to follow the advice of both Innovative Medicines Canada and BIOTECanada regarding next steps for revising the PMPRB Guidelines. Both submissions have been attached for your convenience.

Although we are offering our feedback in response to the current consultation, our response should not be considered as in any way altering our previously communicated opposition to these reforms within the new Guidelines.

Thank you for your consideration on this matter. Should you have any questions regarding our position, please feel free to contact us for further information.

Best regards,



Melissa Koomey  
Vice President and General Manager  
Gilead Sciences Canada, Inc.

August 31, 2021

Via email: [PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca](mailto:PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca)

To whom it may concern:

**Response to: *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)***

This submission is made on behalf of Innovative Medicines Canada (IMC) and its 47 members, who collectively comprise the majority of patentees subject to the Patented Medicine Prices Review Board's (PMPRB) jurisdiction.<sup>1</sup> IMC opposes the July 15, 2021 proposals, which run contrary to the federal government's stated intent to delay the implementation date of the amendments to the *Patented Medicines Regulations* (Regulations) until January 1, 2022 to assist with the ongoing COVID-19 pandemic and, as further described below, will have negative impacts for patentees and many other stakeholders.<sup>2</sup>

The July 15, 2021 proposal to change the international price tests for existing medicines and their line extensions from the highest of the international schedule to the median is arbitrary, inconsistent with the PMPRB's role as a regulator of excessive ceiling prices, and will harm both patentees and other elements of the pharmaceutical supply chain in Canada (e.g., distributors, pharmacies, and generics). PMPRB's own analysis indicates that this change will introduce significant new negative impacts for

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<sup>1</sup> IMC understands that the PMPRB intends to apply Guidelines within the framework of the amendments to the Regulations, which are not yet in force. While IMC is committed to constructive engagement with the PMPRB on the Guidelines, IMC's engagement is not intended and should not be interpreted as supporting the amendments to the Regulations or the Guidelines. On June 29, 2020, the Federal Court of Canada declared that subsection 3(4) of the amended Regulations on the net price calculation is invalid, void, and of no force and effect for being ultra vires the Patent Act. On December 18, 2020, the Superior Court of Québec ruled that same amendment was unconstitutional. IMC continues to have grave concerns about the practicality and legality of the remaining amended Regulations as well as the PMPRB's Guidelines. IMC reserves the right to oppose any aspect of the amended Regulations or Guidelines that exceed the jurisdiction of the Board. It should also be noted that there are a number of Guidelines-related issues that had been identified in previous IMC submissions that have not been addressed and would benefit from more transitional time and discussion (please see IMC's [February 2020](#), [August 2020](#), and [February 2021](#) submissions).

<sup>2</sup> "The main anticipated benefit of the Regulations is to allow drug manufacturers and health system partners to remain focused on responding to the COVID-19 pandemic and provide additional time to prepare for and comply with the changes introduced in the Amending Regulations." Canada Gazette, Part II, Volume 155, Number 14 (June 24, 2021). <https://gazette.gc.ca/rp-pr/p2/2021/2021-07-07/html/sor-dors162-eng.html>



patentees' existing products and line extensions. PMPRB's assessment<sup>3</sup> notes that the proposed changes to the price test and schedule for existing medicines are expected to result in list prices of existing medicines declining on average by 10% in the first year following implementation of the Guidelines.

IMC commissioned a third-party analysis of the July 15, 2021 Notice and Comment Guidelines proposals from an expert consultancy, PDCI. For existing products alone, the adverse impacts would average \$2.39 billion per year or \$23.9 billion over ten years. This reflects more than twice the impact to existing products under the Fall 2020 final Guidelines. This assessment is understated since it does not consider the major anticipated impacts to future products, "lower-of" pricing including the national non-excessive average price (NEAP), and impacts to products launched in the "gap" period which commenced in August 2019.

The proportion of existing products requiring list price reductions would double to 54%, and may be up to 59% in some provinces. The impacted products will face average price reductions of 24.2%. This is an unreasonable and unexpected burden for patentees to bear when the PMPRB arrived at a different excessive price test for existing products following extensive previous consultation.<sup>4</sup> Given that previous impact assessments for international schedule changes were estimated at \$19.8 billion over 10 years, the proposed new price test would front-load and accelerate impacts rather than provide a reasonable transition.

These impacts to patentees are compounded by the fact that they will be felt more rapidly than indicated in previous Guidelines. IMC notes that patentees were previously provided a 12-month transition period by the Board from the coming into force of the Regulations in the October 2020 publication of the final Guidelines, a decision that was reaffirmed by the Board in April 2021.<sup>5</sup>

The July 15, 2021 proposals introducing a new pricing test and change to the transition period are therefore capricious and disruptive for IMC members and other stakeholders, and should be reversed without delay.

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<sup>3</sup> PMPRB [Frequently Asked Questions](#) (August 2021).

<sup>4</sup> For example, on April 2, 2020, the PMPRB Chair issued a statement that "[t]he PMPRB will be making significant changes to the draft Guidelines in response to the feedback it has received." This resulted in the highest of the PMPRB<sup>11</sup> schedule used as part of the final Guidelines. *PMPRB, June 19, 2020, Backgrounder on June 2020 Draft Guidelines: Explanation of Changes from November 2019 Draft Guidelines, page 7, <https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/2020/PMPRB-Backgrounder2020-en.pdf>*

<sup>5</sup> [Message from The Board](#) - April 16, 2021



## **1. The proposed changes to price tests are arbitrary and without a rationale rooted in an excessive pricing standard**

The PMPRB has proposed a major change to how an excessive price for existing products and line extensions is defined without a clear rationale for doing so. All existing<sup>6</sup> and line extension products will be re-benched under the Guidelines at the lower of the medicine's ceiling (e.g., the Non-Excessive Average Price) and the current median of the PMPRB<sup>7</sup> starting on January 1, 2022. The PMPRB subsequently confirmed to IMC that it intends to proceed with this significant change even if the regulatory amendments do not come into force on January 1, 2022.<sup>7</sup>

As a result of its 2020 Guidelines consultation, the PMPRB had previously reached an entirely different conclusion and approach, noting that "the Board has decided to apply the [highest international price (HIP)] test to Grandfathered medicines as a concession to patentees whose expectations may have been raised by [Health Canada's Cost Benefit Analysis (CBA)] and in recognition of the impact of changing the schedule of comparator countries."<sup>8</sup>

This rationale was expressly connected to stakeholder feedback. The PMPRB now proposes to revoke this "concession" but has provided no clear rationale for doing so. The proposed change is unrelated to the implementation date of the regulatory amendments, nor is there any connection back to the CBA consistent with the previous example. The very idea of the Board granting and then revoking "concessions" to patentees suggests that the PMPRB is simply striving to set lower prices, rather than exercising its statutory mandate to detect instances of patent abuse and monitor excessive ceiling prices.

If implemented, this change would reflect an arbitrary and significant change in the Board's policy regarding what constitutes an excessive price for existing products and line extensions. Because no clear rationale has been provided, patentees and other stakeholders are left with the impression that

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<sup>6</sup> The use of the term "Grandfathered" for existing products is inaccurate. No patented medicines have been truly grandfathered (i.e., remaining under the current regulatory system until such time as they are no longer under PMPRB jurisdiction). Rather, existing medicines benefit from a transition period to the new regime, which will be halved by the latest proposal.

<sup>7</sup> As a threshold issue, IMC is alarmed that such a significant change was not made plainly evident and clearly communicated in the July 15 proposal itself, particularly in light of the short window of consultation taking place over the summer months during an ongoing global pandemic. The failure to properly announce or explain this change as a reversal of prior policy in the proposal is a serious red flag that should cause the PMPRB to entirely reconsider proceeding with this consultation at this time.

<sup>8</sup> "Patentees, the biosimilar industry, distributors, industry consultants and some patients and patient groups argue that the MIP should be replaced by the Highest International Price (HIP) for Grandfathered medicines, and make a number of points in support of that position." PMPRB also expressly acknowledged that the CBA assumes maximum list price (MLP) ceilings are generally closer to the "highest" of the PMPRB<sup>11</sup> for Grandfathered products. PMPRB, June 19, 2020, [Backgrounder](#).



this reversal is essentially punitive to further lower prices of patented medicines in light of the government's regulatory implementation delays caused by the ongoing COVID-19 pandemic.<sup>9</sup>

Regardless of whether the Board deems the median to be a reasonable price benchmark, the lack of reasoning in this instance does not provide patentees and other stakeholders with confidence that their concerns regarding an appropriate benchmark or transition period have been heard.<sup>10</sup>

## 2. Halving the Guidelines transition period undermines the stated objective of the most recent regulatory delay

The PMPRB Guidelines finalized on October 23, 2020 provided 12 months of transition from the date of the entering into force of the amended Regulations. As recently as April 16, 2021, the Board issued a decision which confirmed two reporting periods for compliance purposes. This provided a reasonable timeframe for patentees corporate planning to bring the pricing of existing medicines into compliance with the new regime, and also to allow other pharmaceutical supply chain stakeholders to make the necessary adjustments to their business operations. While this change is also not clearly articulated in the July 2021 proposals, PMRPB has confirmed that it intends to require pricing compliance by July 1, 2022. This would have the effect of limiting the transition period to only six months, or one reporting period, which reverses two of the Board's previous decisions providing two reporting periods from the effective date of regulatory amendments.

In addition to being a reversal of its previous decisions on the transition period, this proposal is also at odds with the federal government's rationale to delay the coming into force of the Regulations by six months until January 1, 2022 in support of the ongoing collective efforts to address the most important challenge facing Canadians today: fighting the COVID-19 pandemic.<sup>11</sup> Reducing the Guidelines transition period to six months is inconsistent with and counterproductive to this objective and will increase the administrative burden and cost for stakeholders, an outcome that is contrary to the government's stated intent. Given the clear policy intent of regulatory delays, in our view it is inappropriate for PMPRB to instead advance changes in Guidelines.

While IMC and many other stakeholders continue to disagree with the PMPRB on the policy changes, all parties should be able to agree on reasonable transition and not exacerbating challenges posed by

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<sup>9</sup> Canada Gazette, Part II, Volume 155, Number 14 (June 24, 2021). <https://gazette.gc.ca/rp-pr/p2/2021/2021-07-07/html/sor-dors162-eng.html>

<sup>10</sup> This contrasts with previous Board decisions on the same point of policy made expressly on the basis of stakeholder input. See PMPRB, June 19, 2020, [Backgrounder](#).

<sup>11</sup> See quote above on rationale for regulatory delay. Canada Gazette, Part II, Volume 155, Number 14 (June 24, 2021). <https://gazette.gc.ca/rp-pr/p2/2021/2021-07-07/html/sor-dors162-eng.html>.



the pandemic for a number of parties within the pharmaceutical supply chain.<sup>12 13</sup> IMC submits that the PMPRB should remain consistent with its previous decisions, which patentees and other stakeholders have relied upon for business planning purposes, and maintain two reporting periods from the effective date of the regulatory changes for the purposes of a reasonable transition to a new system.

### 3. Conclusion

In summary, IMC requests that the PMPRB discontinue the arbitrary and harmful proposal to change price tests for existing products and their line extensions. We also maintain that a 12-month transition period from the date that the regulatory changes come into force clearly reflects the federal government's intent to allow all parties to focus on addressing the COVID-19 pandemic.

Moreover, patentees and other pharmaceutical supply chain stakeholders have relied upon the previously announced price tests and transitional timeframe for corporate planning purposes. From an international perspective, they suggest that the Canadian pharmaceutical pricing environment is unstable and subject to change on short notice and without rationale, which in turn impacts on investment opportunities and launch plans for new medicines and vaccines.

We conclude by noting that changes to the PMPRB regime, including these latest proposals, are inconsistent with the federal government's recently announced Biomanufacturing and Life Sciences Strategy, which includes the laudable objective to enable innovation by ensuring world class regulation.<sup>14</sup> IMC strongly supports this position, and is calling on the government to urgently intervene with respect to this matter to prevent further erosion to the predictability of the pharmaceutical and

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<sup>12</sup> As indicated in previous submissions, given the need to secure global approvals, communicate with customers and formularies, and amend product listing agreements and commercial contracts, this is not a reasonable or feasible compliance timeframe. Given that the nature of the PMPRB regime is fundamentally changing (e.g., the regulated price point is moving to a new list-price based system for many products), a reasonable timeline is needed for patentees to be fully aware of their compliance obligations and relevant national average prices, and engage in transitional discussions envisioned under section 75 of the Guidelines, in order to minimize disruption to drug supply chains to the greatest extent possible. Two reporting periods is needed to minimize disruptions for manufacturers, provinces, and other elements of the pharmaceutical supply chain at a sensitive and uncertain time. Significant effort will be needed with public payers, who have unique province-specific requirements, timelines, and processes, as well as other parties within the reimbursement and distribution system, such as wholesalers, distributors, and pharmacies.

[http://innovativemedicines.ca/wp-content/uploads/2021/02/20210212\\_-\\_IMC\\_Response\\_PMPRB\\_Guidelines\\_Notice\\_and\\_Comment.pdf](http://innovativemedicines.ca/wp-content/uploads/2021/02/20210212_-_IMC_Response_PMPRB_Guidelines_Notice_and_Comment.pdf)

<sup>13</sup> Also warranting consideration are previous PMPRB proposals for an 18-month "grace period":

<https://www.reuters.com/article/us-canada-pharmaceuticals-exclusive-idCAKBN20E2LI>

<sup>14</sup> Innovation, Science and Economic Development Canada (ISED) July 2021 [Biomanufacturing and Life Sciences Strategy](#)



vaccine market in Canada. The PMPRB changes can only be harmful to the federal government’s stated objectives of “strengthening Canada’s biomanufacturing and life sciences sector, improving economic growth and ensuring pandemic readiness for years to come.”<sup>15</sup>

IMC is willing to meet to address any questions or provide clarifications with respect to its submission upon request.<sup>16</sup>

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<sup>15</sup> *Ibid.*

<sup>16</sup> IMC takes no position with respect to other elements of the July 15, 2021 consultation, other than to note that they appear to be the only available option given the change to the regulatory implementation date or otherwise act to facilitate the more concerning proposals noted above.

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BIOTECCanada is providing written feedback on the PMPRB's proposed Guideline changes announced on July 15, 2021. BIOTECCanada represents more than 240 member companies which include innovators at all stages of the product lifecycle from basic research and development to commercialization. Some member companies are patentees who report to the PMPRB, but many focus on early research and development in the hopes of bringing new therapies to patients and the health care system in the future, not just in Canada but globally. BIOTECCanada's members include developers and manufacturers of vaccines and the latest technological advances to address unmet medical needs.

As federal and provincial governments look beyond the COVID-19 pandemic, they are identifying the existing gaps and a way forward which would fortify Canada's biotech ecosystem as a more holistic model. BIOTECCanada has consistently called on the government to recognize the connectivity of all elements of the ecosystem and to develop a holistic strategic approach whereby all components are recognized and connected.<sup>1</sup> The government announced July 28, 2021 a five pillar biomanufacturing strategy to guide its undertakings over the period ahead including "enabling Innovation by Ensuring World Class Regulation: ... this will make Canada a more attractive destination for leading life sciences firms to establish and grow. BIOTECCanada has urged the government to partner with the global companies and ensure that whatever capacity is developed is commercially viable in non-pandemic times and supports the growth of Canada's ecosystem. Overall, this will help grow a strong and competitive domestic life sciences sector for a more holistic model which would embrace the multinational companies as foundational partners rather than cost-drivers and, ensure Canada's readiness for future pandemics or other health emergencies.

Health Canada has worked effectively with the industry to deliver solutions to combat the pandemic, most notably therapeutics and vaccines using Emergency Orders and interim measures to accelerate the access to these important new medicines and vaccines. The federal government provided an exemption for COVID-19 therapeutics and vaccines from being subject to the new pricing rules clearly demonstrates that the rules would impact access. During the pandemic, Health Canada delayed the implementation of PMPRB due to these unprecedented circumstances and to give industry time to prepare and analyze impact these Guidelines will have on their businesses. PMPRB is introducing additional proposed changes that would further impact the value of important medicines for Canadians, and importantly has announced these material changes shortly after an announced delay by the Government. This is clearly inconsistent with the stated intentions of Health Canada when announcing the delay in implementation of the changes until January 1, 2022.

The proposed adjustment of the definition of Gap medicines is a significant change which is counter to the intent of the current six-month delay which was intended to provide industry with additional time to prepare for and comply with the changes introduced in the previous amendments. The existing proposed Guidelines were already complicated to interpret, and these latest changes add significant, and unnecessary complexity including the use of two separate sets of comparator countries; one from an active set of Regulations and one from an expired set of Regulations that Health Canada elected to replace. This complexity also appears to be the product of a misalignment between Health Canada and the PMPRB.



Patentees have also recognized there is an additional lack of predictability with these latest proposed Guideline changes. Business decisions are made based on current/anticipated Guidelines and with more changes there is increased business uncertainty. For example, the new proposal to change the price test for most Grandfathered Medicines from Highest International Price (HIP) PMPRB11 countries to Median International Price (MIP) to PMPRB7 countries is unexpected. Again, the government's stated intent of the six month delay in implementation was for the purpose of providing patentees with additional time to adjust to the Guidelines as they were proposed in 2020. In this context, making a significant change to the at this time is completely inconsistent with the stated intent for the delay.

Planning for an appropriate and transparent evaluation of PMPRB reform is important, especially in view of the lack of consensus on the new Regulations and Guidelines and the serious concerns raised by the industry and other key stakeholders – concerns that the inherent market uncertainty and potential for unprecedented price limits will discourage the availability of new treatments for Canadian patients. It remains a concern of BIOTECCanada that PMPRB reform has again been undertaken in isolation and works at counter purposes to these broader “whole of government” approach to industry policy. With the government announcement of a delay to the implementation of the new Regulations and Guidelines are instead met with additional seemingly punitive changes to the proposed Guidelines by PMPRB, irrespective of the proposed Regulations.

The announced implementation delay by Health Canada on June 29, 2021, the biomanufacturing initiative announced July 28, 2021, the investments into the ecosystem announced in the recent spring federal budget, and other policy undertakings, all offer a timely and important opportunity for the government and industry to work in partnership to develop solutions which will ensure Canadian patients have access to the new technologies emerging from the global industry and establish the industry as an important partner in enhancing the competitiveness and accelerating the growth of Canada's biotech ecosystem. This presents an important and timely opportunity for Canada to generate even more positive returns intrinsic to a successful biomanufacturing industry. From this success comes the potential for a modern, effective and competitive regulatory environment ensuring safety, while encouraging the development and adoption of innovative new products and services. A high performing regulatory system should be predictable, efficient, consistent, and transparent, so as not to present barriers to global business investment, innovation and ultimately, economic growth and values with improved outcomes that benefit Canadians. The industry is developing game-changing innovative therapies and technologies such as gene editing, artificial intelligence, and nanotechnology. A consistent, predictable and competitive regulatory process will help ensure Canada is remains a destination for new therapies and treatments over the years ahead.

Sincerely,



Andrew Casey  
President and CEO

References:

<sup>1</sup> [Publications - BIOTECCanada \(biotech.ca\)](https://www.biotech.ca/publications)