CAPDM Driving | Healthcare

August 31, 2021

Sent via email: pmprb.consultations.cepmb@pmprb-cepmb.gc.ca

Re: The PMPRB proposal to change the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions

To whom it may concern;

The Canadian Association for Pharmacy Distribution Management (CAPDM) would like to take this opportunity to highlight some of our concerns regarding the July 15, 2021 Patented Medicine Price Review Board (PMPRB) guideline proposal. **CAPDM and our distribution members oppose 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 all pharmaceutical supply chain stakeholders as well as patients.

CAPDM and its members are very much concerned with the proposed changes to the international price tests for grandfathered medicines and their line extensions as well as the proposed shortened transition period for grandfathered and gap medicines.

Changes to the International Price Tests

In the first half of 2020, following consultation with CAPDM and its members, the MIP (median of international price) price test for existing drugs was adjusted to HIP (highest of the international price).

The July 15, 2021 proposal to change the international price tests for existing medicines and their line extensions from HIP of PMPRB11 to MIP of current PMPRB7appears arbitrary. It is difficult for CAPDM to reconcile PMPRB's role as a regulator of excessive ceiling prices with this punitive guideline modification. This proposal will be very harmful to pharmaceutical supply chain stakeholders, including our distributor members. The information provided by the PMPRB suggests that the impact will be more than any previous proposal by the PMPRB to date with little rationale and justification. As a result of these guidelines, we anticipate a deepening funding erosion for downstream pharmaceutical actors (distributors and pharmacies). **The estimated impact on distributors alone is projected to be a $40-60 million funding reduction per year**. **This is double to triple the previous negative impact of the earlier PMPRB guidelines. In order to offset this loss, CAPDM foresees distributors members having to cut costs by reducing service levels and/or postponing or foregoing investments to maintain the critical drug distribution infrastructure which could ultimately lead to reduced patient access to the medication they require.**

Under the HIP pricing test in the previous guidelines, there would have still been a material impact on wholesalers, but the industry would have been better able to weather the distribution funding reduction vs. this recent reversal back to an MIP price test

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, pharmaceutical supply chain stakeholders are left with the impression that 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.

The Federal Court of Appeal (FCA) recently reiterated that the PMPRB's mandate is to ensure to carry out provisions in the Patent Act which are to prevent patent abuse. They are not to enforce "reasonable pricing, price regulation or consumer protection at large". It can be argued that by moving from the high to the median of Scheduled Countries, this no longer addresses patent abuse, but rather enforces 'reasonable pricing'. The FCA also determined that should PMPRB stray away from Guidelines or long-standing practices, that the PMPRB needs to explain why it has deviated from these practices. In the Notice & Comment, PMPRB does not explain why it has moved from the high of the PMPRB11 to the median of the PMPRB7.

Shortened Transition Period

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. With new regulations scheduled to take effect January 1, 2022 and the proposed guidelines requiring 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.

A minimum twelve-month transition period from the date that the Regulations come into force is needed to allow all parties to effectively plan and execute a multitude of pricing conversions. Many actors will be affected by such changes and the work involved requires much coordination (please refer to CAPDM's February 15, 2021 submission to the PMPRB on compliance timelines for greater details). CAPDM would like to remind PMPRB that a multi-stakeholder group needs to be formed in terms of coordination/timing of price changes with provincial bodies to ensure a clear timeline for pricing adjustments and washout periods to prevent localized drug shortages.

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. 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.

Summary

This is an unreasonable and unexpected burden for distributors to bear when the PMPRB arrived at a completely different excessive price test for existing products and transition period following extensive previous consultations. **The July 15, 2021 proposals introducing a new pricing test and change to the transition period** appear to be high-handed and are extremely disruptive for CAPDM members and other stakeholders, and **should be reversed without delay**.

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Without any discernable rationale or context, these new proposed guidelines were released two weeks after Health Canada delayed the implementation of new PMPRB regulations to January 1, 2022. This was a shock to our sector and created confusion, uncertainty, and angst. The consultation period for the new proposed guidelines is short, falls in the middle of summer, a federal election underway and, most importantly, comes at a time when distributors and pharmacies are unusually consumed by pandemic efforts and vaccine deployment. This situation has unfortunately been incredibly disruptive to supply chain stakeholders and to the Canadians that rely on our services.

The lack of reasoning does not provide CAPDM and our members with confidence that our previous recommendations and concerns regarding an appropriate benchmark or transition period have been heard.

Recommendations

In light of the above, CAPDM recommends:

1. PMPRB does not introduce a new price test for Grandfathered medicines and their line extensions
2. PMPRB maintains 12-month transition timeframe from the date that Guidelines and Amended Regulations come into force
3. New Guidelines and Amended Regulations are not decoupled in their timeline for implementation
4. PMPRB to work with multi-stakeholder group to plan effective and consistent transition process
5. PMPRB to uphold commitment to evaluating and monitoring the impact of the reforms on the broader eco-system and particularly on the unintended consequences to the essential pharmaceutical distribution infrastructure

Pharmaceutical distributors are essential players in Canada's health system. Without our services, medicines cannot get to Canadians. At this time, our member organizations believe that it would be prudent for the PMPRB to pause the ongoing consultation.

Distributors, pharmacies, and manufacturers have been a willing partner to work with the government on shared and common objectives, supporting the sustainability of the health care system, affordability, and access to prescription medications. We have demonstrated our unwaveringly commitment to Canadians and health systems throughout the pandemic as critical partners in the timely delivery of products and services – in mitigating supply chain challenges and in helping Canadians to access vaccines conveniently in virtually every community across the country. Without our services, medicines cannot get to Canadians.

In summary, **CAPDM 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.**

CAPDM and its members would be available to work with the PMPRB staff as part of a multi-stakeholder group to effectively plan such a transition as well as the ongoing monitoring and evaluation of the impacts of the new regulations and guidelines. We welcome the opportunity to submit our comments to the PMPRB and are available to meet to answer questions or provide further clarification.

Sincerely,

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