February 12, 2021

Via email: 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 and the timeline for compliance (January 15, 2021)

This submission is made on behalf of Innovative Medicines Canada (IMC) and its 45 members, who collectively comprise the majority of patentees subject to the Patented Medicine Prices Review Board's (PMPRB) jurisdiction. IMC has significant concerns with and is opposed to the January 15, 2021 proposal to halve the Guidelines transition period to six months.[1]

The PMPRB Guidelines finalized on October 23, 2020 provided twelve months of transition from the date of the entering into force of the amended *Patented Medicines Regulations* (the Regulations) for patentees to bring the pricing of existing and "Gap" medicines into compliance with the new regime. The Notice and Comment proposes to limit this important transition period to only six months but provides no rationale for this material change to the final Guidelines, which will adversely impact IMC members and other patentees unless amended.

This proposal also appears to be at odds with the federal government's rationale to delay the coming into force of the Regulations by six months until July 1, 2021 in support of the ongoing collective efforts to address the most important challenge facing Canadians today: fighting the COVID-19 pandemic. As stated in the Regulatory Impact Analysis Statement (RIAS) issued with the Regulations: "[t]he main anticipated benefit of the Regulations is to allow drug manufacturers and health system partners to remain focused on responding to COVID-19 and allow stakeholders enough time to respond to and be

[1] IMC understands that the PMPRB intends to apply Guidelines within the framework of the amendments to the Patented Medicines 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 and August 2020 submissions).

informed on new guidelines currently being developed by the PMPRB."[2] Reducing the Guidelines transition period to six months is inconsistent with and counterproductive to this objective and would increase administrative burden contrary to the government's stated intent.

While IMC and many other stakeholders continue to disagree with the PMPRB on the policy changes themselves, all parties should be able to agree that 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.

Even in the absence of a global pandemic, the proposal is unrealistic given business realities. Patentees need more than six months to adapt to the new regime for existing and 'Gap' products. 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.

The proposed transition period is in fact much shorter than six months: PMPRB will only be able to confirm new price ceilings to patentees mid-way through the July to December 2021 period. As such, the proposed transition would likely amount to a matter of months.[3] 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.

Furthermore, 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.[4] A solution to

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[2] Canada Gazette, Part II, Volume 155, Number 2 (January 20, 2021).

[3] Patentees are required to submit the semi-annual Form 2 report based on the new regime for the January to June 2021 reporting period by July 30th, 2021. The PMPRB will then have 45 days to provide patentees with their respective compliance reports which will contain information on the new price ceilings. Consequently, patentees will only receive compliance information on the new price ceilings by mid-September 2021 at the earliest to review compliance information for all of their patented medicines, determine if an MLP calculation has been significantly impacted by the reporting of benefits and submit a review under Guidelines section 75 if applicable, and reduce list prices where necessary in all provincial/territorial jurisdictions as per their respective policies and timelines.

[4] Also warranting consideration are previous PMPRB proposals for an 18-month "grace period": https://www.reuters.com/article/us-canada-pharmaceuticals-exclusive-idCAKBN20E2LI

implement new Guidelines in July is feasible and would be straightforward to implement from a logistical perspective.

In summary, a minimum twelve-month transition period from the date that the Regulations come into force is needed to allow all parties to focus on addressing the COVID-19 pandemic. The previously proposed timeline set out in the October 2020 final Guidelines was both more reasonable and operationally feasible than the current proposal. No rationale has been provided for halving the previous timeframe, which also appears to be inconsistent with the RIAS accompanying the Regulations.[5] Given the ongoing pandemic and for the reasons set out above, the proposal in the Notice and Comment should be amended to provide a minimum of two reporting periods totalling twelve months (July 1, 2022) for the transition. Patentees remain open to working with PMPRB compliance staff in this regard.

Thank you for providing the opportunity to comment on the proposals. IMC is willing to meet to address any questions or provide clarifications upon request.

[5] With respect to Gap Medicines, the Notice and Comment document proposes to extend the date of first sale to the new coming-into-force date of the Regulations on July 1, 2021. IMC takes no position with respect to this proposed change, other than to note that it appears to be the only available option given the change to the implementation date.