February 15, 2021

Douglas Clark, Executive Director
Patented Medicine Prices Review Board (PMPRB)
Box L40|Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario, K1P 1C1

RE: Notice and Comment - Change to the definition of Gap medicines and the timeline of compliance

Dear Mr. Clark:

On behalf of the member companies of BIOTECanada, I am writing in response to the Patented Medicine Prices Review Board's (PMPRB) request for comments on the change to the definition of Gap medicines and the timeline of compliance.

BIOTECanda remains concerned with the Regulations Amending the Patented Medicines Regulations and the final PMPRB Guidelines. While the implementation of the Regulations has been delayed six months to July 1, 2021, this delay fails to address many of the fundamental concerns raised by the biotechnology industry. BIOTECanada is committed to constructive engagement with the PMPRB, however, the recommendations provided in this consultation response should not be interpreted as supporting the Regulations or the Guidelines.

Throughout the 2020 Guideline consultation period, the biotechnology industry has highlighted the serious gaps in detail relating to the implementation of the Guidelines. PMPRB staff have stated in those cases where clarity is not established on how the new regulations will be applied to products, they will undertake decision making on a case-by-case basis. This is despite PMPRB committing at the beginning of the reforms process the resulting changes would result in very clear "brightlines" for all stakeholders, including patentees. This approach creates significant vulnerability for the Canadian system of access. Not being able to have a clear and appropriate value-based decision process for new products entering the market, puts Canada at a distinct disadvantage compared to other jurisdictions. New product launches will instead be focused on markets where this certainty is provided, and where product value and price are evaluated collectively to help ensure the most efficient use of therapies is serving patients who can truly benefit.

With respect to the two proposed changes in this Notice and Comment consultation, BIOTECanada offers the following recommendations.

Compliance Timelines for Grandfathered and Gap Medicines:

Under the Guidelines published October 2020, compliance with the Maximum List Price (MLP) for Grandfathered and Gap medicines would be assessed after two reporting periods. The PMPRB is instead proposing to reduce this to one reporting period so the December 31, 2021 would remain the operative date for assessing compliance.

BIOTECanada strongly recommends the PMPRB maintain its original approach of assessing a patentee's compliance with the MLP for Grandfathered and Gap medicines after <u>two</u> filing periods.

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The Health Canada Regulatory Impact Statement (RIAS) states the delay in implementation would provide the biotechnology industry with additional time to prepare for the new reporting obligations as the COVID-19 pandemic continues to challenge all stakeholders. However, with the severe impacts of the second wave of the pandemic, comes the realization the challenges of the pandemic will continue to strain existing systems. Truncating the compliance timeline to less than 4 months, places even more undue burden on the biotechnology industry, in addition to key health system stakeholders, at a time when focus should be on ensuring continued supply of medicines and vaccines to Canada and ramping up the economic recovery.

Reducing compliance timelines to one reporting period poses operational and feasibility challenges and will cause impossible timelines and situations not only for patentees, but also for the PMPRB, payers and a broader set of stakeholders including wholesalers and pharmacies.

The proposed timeline, which is only approximately 4 months from an operational perspective, does not provide patentees with the time to implement a price reduction. Further, it will cause issues in the distribution chain, as pharmacies and wholesalers will have less time and notice to appropriately manage their inventory (e.g., order less so that they can deplete the inventory they purchased at the higher cost). The short timelines also may not align with provincial price change notification policies, so the 'public' price on formularies on December 31, 2021 may not reflect the reduced price. The result will be an increase in the number of investigations PMPRB will have to open for an issue that is outside of the control of the patentee. The example in Box 1 outlines the level of complexity and challenges in operationalization that will be avoided if PMPRB maintains its original approach of assessing a patentee's compliance for the MLP for Grandfathered and Gap medicines after two filing periods.

Box 1 – Case Example:

In the case of Quebec, patentees must provide notice of a price change approximately 7 weeks ahead of time on a specific date; for implementation of price change mid-December. If a patentee were unable to meet this timeline, because the PMPRB was not able to provide the final resolved compliance reports in time, the next formulary update in Quebec would be in 2022, which would leave patentees out of compliance at the end of 2021 even if they would like to implement a price decrease.

Between mid-September and end-of-October, a patentee would only have approximately 45 days to work with PMPRB on the DINs that would need a re-setting of the NEAP, as stated in Section 75 of the new Guidelines. There would be hundreds of DINs in this situation requiring review, making it operationally challenging for this to be done within the timelines. Patentees will not have enough time to approve the new price internally and take all the steps needed to send out communications to all payers for implementation prior to the end of 2021.

The operational challenges will have broader impacts beyond the Quebec context. All public payers, private payers, pharmacy benefit managers, wholesalers, distributors, and pharmacies in the country will be required to adjust to significant and unplanned work to updating their price lists when hundreds of DINs have price changes all at once. There will be contracts to be amended with public and private payers, institutional accounts, buying groups. This cannot be operationalized with tight deadlines on the patentee side, and by all these downstream players. This timeline will be a serious burden for government payers where it sometimes takes months for them to approve and obtain senior government signature on even the simplest of contract amendments. There might be a lot of unintended non-compliance and pricing discrepancies between these different players because operationalizing the change will be challenging under such a tight deadline.

Definition of Gap Medicine:

The original definition of Gap medicines under the new Guidelines applies to medicines for which a DIN was assigned on or after August 21, 2019 and that were first sold in Canada prior to January 1, 2021. The PMPRB is proposing to extend the date of first sale to the new coming-into-force date of July 1, 2021.

BIOTECanda members agree with the proposed change in definition of a Gap medicine to align with the new July 1, 2021 regulatory implementation date. It is understood the PMPRB is also of the view that, not only must the first sale of a Gap medicine be made before July 1, 2021, the NOC must also issue before July 1, 2021. This is not explicitly set out in the Guidelines and ignores the fact that the PMPRB assumes jurisdiction on first sale or first NOC, whichever is earlier. The definition of Gap medicine should therefore not require both a NOC and first sale before July 1, 2021.

The definition of Gap medicines allows PMPRB to set clearer distinctions in the Guidelines for medicines subject to new the Regulatory factors (as opposed to "Grandfathered" medicines) but for which introductory prices will have been assessed prior to the effective implementation of the new Regulations or Guidelines. While the 'gap' period in August 2019 was originally intended to last four months, the new effective date of July 1, 2021 means some Gap medicines will have been sold for almost two years. The use of the median international prices for Gap medicines unnecessarily differentiates this group from grandfathered drugs. To facilitate the transition and minimize market disruptions, it is recommended the PMPRB review all existing drugs (both Grandfathered and Gap) using the same MLP calculation: the lower of the ceiling under the current guidelines and the highest international price. Prices that are in compliance with existing Guidelines should be recognized for that.

The PMPRB Regulatory and Guideline changes come at a critical time for Canada and Canadian patients. Aside from the reality of both the short term and longer-term impact of the COVID 19 pandemic, the nature of how healthcare solutions are discovered and ultimately accessed is undergoing unprecedented levels of change. Rapidly emerging technologies such as stem cell, gene and cell therapies, immuno-oncology therapeutics, CRISPR editing and new vaccines stand to dramatically improve treatment and even provide cures for health challenges, including rare diseases.

Despite significant feedback submitted by a cross-section of stakeholders during PMPRB's consultations, BIOTECanada remains concerned by the volume of issues left unaddressed in the October 2020 Guidelines. It is strongly recommended the PMPRB review its approach to eliminate the uncertainty, complexity and regulatory burden that result from the reformed Guideline package proposed. This should be done in consultation with patentees through Technical Working Groups, to ensure the Guidelines are operational, fair and offer the predictability needed to ensure Canada remains a priority destination for new medicines.

Thank you for this opportunity to provide input on this consultation. BIOTECanada and its member companies are fully committed to working cooperatively with PMPRB to continue to establish a policy that ensures the health of Canadians and provide for a sustainable health care system.

Sincerely,

Andrew Casey
President & CEO