GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario
Canada L5N 6L4

T 905 819 3000
F 905 819 3099
www.gsk.ca

February 14, 2021

Dr. Mitchell Levine
Chair of the Board
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
1400-333 Laurier Avenue West
Ottawa, ON K1P 1C1

RE: GSK's submission regarding Notice and Comment – On the change to the definition of Gap medicines and the timeline for compliance (January 15, 2021)

In January 2021, the Government of Canada confirmed that the coming-into-force of the amended Patented Medicines Regulations would be delayed until July 1, 2021 due to the ongoing pandemic. GSK welcomes the Government of Canada's recent decision to extend the planned implementation date of the new PMPRB pricing regulations. However, we still have concerns about the overall direction of the new PMPRB pricing reforms and the effect these changes will have on Canadians' access to innovative medicines, as well as on the country's ability to attract new life-sciences investments.

Since the pandemic began, GSK has worked globally and locally to marshal our scientific expertise, talent and technology to respond to COVID-19. The announced delay means one less immediate distraction from our goal of being part of the pandemic solution.

As a science-led global healthcare company, GSK is actively involved in the development of a variety of innovative COVID-19 solutions. For instance, GSK has actively pursued multiple collaborations with companies and research groups around our innovative vaccine adjuvant technology. GSK believes that the use of an adjuvant will be of importance in a pandemic situation where there is significant demand for a vaccine, since it may allow more doses to be produced from less ingredients and therefore enable manufacturing at scale. GSK is rapidly scaling-up the manufacturing capacity of our AS03 pandemic adjuvant at sites across our global manufacturing network, and

GSK's Ste-Foy, QC manufacturing site is currently playing a key role in the production of pandemic adjuvant for various candidate COVID-19 vaccines currently in development.

Further, alongside our work to develop adjuvanted COVID-19 vaccines, GSK continues to work hard to find other ways to help tackle the pandemic, including exploring potential therapeutic or treatment options for COVID-19 patients.

GSK welcomes the Government of Canada's January 2021 decision to extend the planned implementation date of the new PMPRB pricing regulations to July 1, 2021.

However, GSK respectfully submits that the PMPRB's recently published Guidelines Proposal to shorten the implementation time horizon from 12 to 6 months (i.e. from two standard reporting periods to one standard reporting period) is impractical and carries a high administrative burden. Consequently, GSK recommends that the PMPRB return to its original plan for a 2-reporting period phase in (i.e. 12 months), beginning as of the new effective date of the regulations.

It is widely acknowledged that the PMPRB pricing reforms enacted by the Government of Canada in August 2019 are without question the most significant and far-reaching pharmaceutical pricing reforms our country has seen over the last 30 years. Owing to the breadth and complexity of the reforms – as well as their impact on industry – PMPRB staff had indicated in various public and private forums in the months following the Government's August 2019 announcement that patentees would be afforded an 18-month transition period, which was presumably intended to allow sufficient time for companies to install and operationalize the necessary systems, and to collaborate with provinces and wholesalers so as to comply with the new pricing requirements.

For instance, in February 2020, the Executive Director of the PMPRB, Douglas Clark, indicated in an interview with *Reuters* that industry would be provided an 18-month grace period to bring the prices of thousands of patented medicines and vaccines into compliance with the new rules.[i]

This guidance from the PMPRB to manufacturers seemed sensible and reasonable given that, on other prior occasions over the years where the PMPRB had made substantial updates to its pricing Guidelines, manufacturers were able to rely on an appropriate transition period to come into compliance with the Board's new rules and guidelines. For example, in the wake of the PMPRB's 1994 pricing reforms (which were indeed far less complex than the August 2019 reforms), a transition period of 3 years was provided.

[i] Exclusive: Canadian regulator considers changes to new drug pricing plan | Reuters

Under the PMPRB's latest proposal, this 18-month transition window would be shortened to 6 months. Additionally, when coupled with required additional administrative processes involving publicly tendered vaccines (i.e. allowable Maximum List Price reconsiderations for Grandfathered vaccines with uncharacteristically low NEAPs[ii]) the actual time to have the maximum allowable price confirmed by the PMPRB, and brought into compliance would effectively be only 8-12 weeks as a practical matter.

Considering this, GSK recommends that the PMPRB return to its original plan for a 2-reporting period phase in (i.e. 12 months), beginning as of the new effective date of the regulations. Our reasons in support of this recommendation follow below:

1) The Shortened Reporting Period Proposed by the PMPRB is Misaligned to Provincial Processes

The PMPRB's proposal is misaligned to the timing of standard processes established by provinces for pricing changes. For example, the Province of Ontario, which has the country's largest public drug program, requires pricing changes to be made in the Spring (e.g. April), not in the Fall as is proposed under the new PMPRB proposal. Several other provinces operate under similar annual time horizons. In this regard, it is important to note that for publicly listed products, price decreases ~~s~~should not be taken until accepted by the provincial formularies and made effective. Otherwise, the formularies' maximum reimbursable prices will not be reflective of the price decreases, creating confusion at the pharmacy level, and potentially leading to claw-backs.

Finally, given the excessively tight implementation window proposed by the PMPRB there is some question as to whether manufacturers would be able to immediately satisfy certain requirements of Quebec's '*Regulation Respecting the Conditions Governing the Accreditation of Manufacturers and Wholesalers of Medications*,' specifically the stipulation that the Province of Quebec will not pay more than other provinces for medicines.

2) The PMPRB's Proposal to Shorten the Transition Period from 18-months to 6-months is Simply Unworkable for Vaccines that Require NEAP Adjustments

The October 2020 Final PMPRB Guidelines outline a process for MLP reconsideration requests (see: Section 75). GSK notes that PMPRB's shortened implementation timeline

[ii] Many patented vaccines have Government contracts and due to the negotiated pricing, their National Estimated Average Prices (NEAPs) are significantly different from their current list price. Therefore, most patentees will need to request a "NEAP exception" for most of their vaccines, in order to confirm their Maximum allowable list price. It is unknown how long this process could take, but a conservative estimate is likely to be at least two months given the volume of requests likely to be submitted to the PMPRB, and the nature of the information that would need to be reviewed. Based on this assumption, patentees would only know the vaccines' MLP by October, and would then have three months or less to adjust pricing in order to comply by December 31, 2021.

would leave insufficient time for patentees and the PMPRB to appropriately assess and resolve the number of reconsideration requests and subsequent price changes that would need to occur. In putting forward this proposal to shorten the implementation timeline from 18 to 6 months, it seems likely that the PMPRB is underestimating the volume of Section 75 requests that would need to be processed. For instance, of GSK's total 25 vaccine DINs reported to PMPRB, GSK projects that approximately 80% of these vaccines would have uncharacteristically low NEAPs due to customer contracts and benefits. As such, GSK will have to complete about 20 unique MLP reconsideration requests and receive the results of those from the PMPRB within 4.5 months.

As an example, we invite the PMPRB to consider that HPV vaccines typically have low NEAPs as a result of customer contract benefits and thus would require MLP reconsideration requests. Thus, for a HPV vaccine DIN, if one imagines how the Section 75 process could play out according to the PMPRB's shortened implementation period, the adjusted MLP would not be expected to be received until September 15, 2021 at the earliest (i.e. 45 days from 2021 first half filing) providing 30 days or less after that to submit an MLP reconsideration request.

From approximately October 15, 2021 on, PMPRB staff would then have to consider GSK's request (alongside dozens of similar requests from other Canadian vaccine manufacturers) and try to provide a decision regarding GSK's compliance by December 31st, 2021. This example illustrates the timeline for simply one vaccine DIN, while in fact GSK would have to complete price adjustments for approximately 20 DINs in total.

Thus, considering PMPRB's timeline coupled with compounded requests from a number of manufacturers in addition to GSK, an outlook to complete the process for all imminent MLP reconsideration requests by year's end is simply unfeasible.

Conclusion

GSK remains concerned about the overall direction of the new PMPRB pricing reforms, and the unintended consequences these changes will have on Canadians' access to innovative medicines, as well as on the country's ability to attract investment to our life-sciences sector.

We conclude by noting that GSK's key positions with respect to the new PMPRB Regulations and Pricing Guidelines are substantively consistent with the input our company has provided in previous submissions (including our August 3, 2020 submission which we attach as an Appendix to this letter), and we would refer any readers of this letter to those earlier documents rather than reiterate those comments at length.

GSK is not alone in expressing these concerns; they are shared by a number of stakeholders as well, including key provinces, as well as industry groups and patient groups. Indeed, GSK has reviewed the 112 submissions to PMPRB's most recent

consultations that were publicly posted online, and by our own assessment, over 80% of the respondents were either outright opposed to – or have expressed serious reservations with – the new pricing regime for patented medicines.

Troublingly, that is even more than the percentage of stakeholders opposed to the first draft of the Guidelines in 2019. Specific comments included:

- Two-thirds of respondents cited concerns about access to innovative medicines;
- Many respondents noted that the new Guidelines are 'too complex' and will create 'uncertainty and unpredictability,' which could delay or impact new launches; and,
- A number of stakeholders expressed frustration that the PMPRB's consultation process did not allow them to be meaningfully engaged regarding their concerns.

While the new pricing Guidelines proposed by the PMPRB are flawed, and the proposal to shorten their implementation period from 18-months to 6 months only serves to compound the unintended negative consequences of the new pricing rules, there is a better way. GSK strongly supports the call by Canada's innovative pharmaceutical industry for an opportunity to have a solutions-oriented dialogue with the Government of Canada, the PMPRB, provinces and territories, patient groups and others to find a balanced approach to modernizing and improving Canada's 30-year old pricing regime.

Through dialogue, we can find ways that meet the legitimate needs of manufacturers for predictability, while ensuring sustainability and access to innovation for patients.

In the meantime, GSK respectfully submits that the PMPRB's particular proposal to shorten the implementation timeline for the new Guidelines from 18-months to 6 months is administratively unworkable, and should be adjusted to allow for a more feasible transition period as of the final effective date of the new regulations.

GSK would be pleased to address any questions the PMPRB Board may have regarding our submission, upon request.

Thank you for your consideration,

Ranya El Masri
Head – Government Affairs and Market Access
GlaxoSmithKline Inc.