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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 re Notice and Comment – July 2021 Draft Guidelines

Dear Dr. Levine:

I am writing on behalf of GlaxoSmithKline Inc. (GSK) to share our concerns regarding the Patented Medicines Price Review Board's (PMPRB) proposed amendments to the October 2020 PMPRB Guidelines.

Throughout this reform process, GSK has been an active respondent to the multitude of consultations, and I would begin by noting that GSK's key positions with respect to PMPRB reforms have been clear. We remain concerned about the overall direction and the impact that the new Patented Medicines Regulations will have on Canadians' future access to innovative medicines, as well as the country's ability to attract investment in our life-sciences sector.

From the outset, GSK has publicly and consistently acknowledged that payers have legitimate concerns around sustainability, and in particular are calling attention to the growing cost of biologics and specialty medicines as a proportion of overall drug spending. While "the sky clearly is not falling" in Canada when it comes to the affordability of patented medicines (i.e. the domestic price trends in the PMPRB's

2019 annual report show that prices of patented drugs increased by just 1.3% in 2019 on the basis of list prices, and actually may be decreasing on a net price basis when confidential rebates are factored in), GSK does recognize that industry has a necessary and important role to play in coming to the table with ideas and solutions to help ensure sustainable access and affordability for Canadians for years to come. Where possible, GSK has sought to bring forward practical solutions and ideas to help make aspects of the new Guidelines more workable for regulated parties, as well as to payers.

For instance, as you know, GSK worked with other willing parties to bring forward a tangible solution to address certain unintended risks posed to provincial and territorial vaccines tendering arrangements in earlier drafts of the Guidelines. By adding Section 76 to the June 2020 Guidelines, the PMPRB appears to have acknowledged that, pursuant to the feedback received, using NEAP as a price-setting tool may be problematic in some cases for publicly-tendered vaccines (as evidenced in GSK's August 2020 submission). Fundamentally, GSK sought to be constructive by proposing other solutions on this issue.

Canada Needs a Predictable Pricing and Regulatory Regime for Innovative Medicines and Vaccines

On July 15, 2021, the PMPRB unexpectedly announced a further round of amendments to the purported "Final" October 2020 Guidelines. The proposed changes represent a major change to how an excessive price of Grandfathered medicines is defined. The Board is proposing that all Grandfathered medicines be re-benched under the Guidelines at the lower of the Non-Excessive Average Price and the current median international price of the PMPRB7, essentially foregoing the application of the highest international price test of the PMPRB11.

This is a radical departure from previous discussions and understandings that had been reached between the industry, the PMPRB and the government through the consultation process. This latest change represents regulatory unpredictability "on steroids".

I will begin by outlining GSK's concerns with the proposed amendments to the Guidelines announced in July 2021, which are the subject of this consultation.

The October 2020 Guidelines Were Characterized by the PMPRB as "Final"

On October 23, 2020, the PMPRB stated that its published Guidelines would be the final iteration of the multi-year overhaul in patented medicine pricing regulations. The release of these (ostensibly) final guidelines represented a culmination of a 5-year exchange between stakeholders and the PMPRB. The October 2020 Guidelines thus became the foundation for GSK's, and presumably also the rest of the Canadian pharmaceutical industry's, business planning activities. Consequently, investment and hiring decisions that have already been made are based on this set of rules.

GSK and other innovative life sciences companies had every reason to believe that the October 2020 Guidelines were indeed final. Those Guidelines were described by the PMPRB as the product of "the most intensive and far reaching public consultation in our more than three decades long history." Moreover, there was an acknowledgement made by the PMPRB of "concessions" that had been made in response to stakeholder feedback, including feedback from the industry. In particular, and very importantly, the PMPRB chose in October 2020 to revert to a HIP PMPRB11 pricing test for Grandfathered medicines and vaccines. (While the Board was careful to avoid saying that it had dramatically overshot the Government's published regulatory Cost Benefit Assessment by proposing to introduce an MIP PMPRB11 pricing test, there was nevertheless an appropriate acknowledgement by the Board of this possibility.)

So as not to unduly add to the length of this submission, I will not restate GSK's key comments on earlier versions of the Guidelines, leading up to the alleged Final October 2020 Guidelines (our June 2020 Draft Guidelines Submission and February 2020 submission are attached as an appendix to this letter). However, I am obliged to point out that by now proposing to scrap the compromise of HIP PMPRB11 test for Grandfathered medicines and introduce an MIP PMPRB7, the Board is once again on the verge of losing sight of Cabinet's policy intent, as captured in the CBA.

As GSK previously noted:

> *GSK would like to draw your attention to Health Canada's May 2019 published version of the Cost-Benefit Analysis and Regulatory Impact Assessment (CBA), which clearly indicates that the longstanding Highest International Price Comparison (HIPC) test would be preserved (at least for existing medicines). The CBA was used to inform the public discussions and debate surrounding the new pricing regulations that were put forward for consultation in the Canada Gazette. In her public statements about the proposed reforms, the former Minister of Health, as well as senior officials from her department and across government, generally referred to facts and figures that were drawn from that document. As such it is a fair interpretation that that the price tests mentioned within the CBA form the roots for which the government hopes to anchor its reform intentions. In proposing to use the Median International Price (MIP) the PMPRB seems to show a disregard for the true-intentioned nature of Minister and the value that the CBA holds.*

As a company that employs nearly 2,500 people across Canada in high value jobs, invests over $70 million per year in Canadian R&D and contributes approximately $194 million every year to Canada's GDP, GSK is concerned that the PMPRB continues to propose changes on topics that have been extensively discussed while stripping away key points of concession and creating regulatory uncertainty.

We understand that the PMPRB wishes to implement its long-awaited modernization but equating the HIP of the PMPRB11 to the MIP of the PMPRB7 is simply an unjustified attack on the commercialization and access of innovative medicines in Canada. It is often the case that pricing in comparator countries that comprise the lower 75th percentile of PMPRB11 is largely the same of those in the similar percentile band of the PMPRB7. Given this correlation, one could ascertain, that if moving from HIP PMPRB11 to MIP PMPRB7 simply does not equate, why is the PMPRB attempting to use this test as a price setting tool?

To further iterate the significant impact of this stark variation, GSK's forecasted assumptions show nothing short of double-digit incremental impact to list prices on several of our established medicines due to MIP PMPRB7. This price reduction is over and above the savings that would have been achieved from the HIP PMPRB11 test, which itself was a reduction over the HIP PMPRB7, a pricing test which predates these reforms.

From the outset of this reform exercise, GSK has sought to impress upon the PMPRB Board and Staff the unrealized impact that cumulative double-digit drug price reductions will have on innovative life sciences companies. These constant policy shifts and challenges significantly stifle manufacturers' ability to make long-term investment decisions that create jobs. They also stifle local research collaborations.

The PMPRB is 'Grandfathering' in Name Only

One could look to the PMPRB's persistent misuse of the term "grandfathering" as another example of where regulatory predictability is entirely lacking. By definition, grandfathered implies that an existing entity, whether in relation to a law, policy, person, or medicine, is not covered or is exempt from the new law, in this case the new Guidelines. As such it is confusing, and frankly a bit disingenuous, to refer to a patented medicine as a "grandfathered product" while simultaneously subjecting that very same medicine or vaccine to a radically different pricing test than has historically been the case.

The notion of grandfathering is not a new concept in regulatory law and public administration. For countless other panels, tribunals and regulatory bodies both at home and abroad, grandfathering, carried out in good faith, is a well-established process. Its fundamental purpose is grounded in the that fact that difficult and controversial policy changes are, at times, necessary or unavoidable. However, where possible, a company's existing footprint should not be reprehended to deliver future-oriented changes.

In the case of the proposed changes to the Guidelines announced in July 2021, the abrupt policy reversal on grandfathered medicines is accompanied by little rationale or explanation for doing so. The proposed change to Grandfathered medicines is clearly not a consequential amendment due to the change in the implementation date of the regulatory amendments, nor is there any logical connection back to the

CBA, as noted above. The very idea of the Board granting, in October 2020, and then revoking, in July 2021, important "concessions" [as described by the PMPRB] to patentees suggests that the PMPRB is simply striving to further lower prices beyond the materially lowered price ceilings of the October 2020 Guidelines, rather than exercising its statutory mandate to deal with instances of patent abuse (i.e. policing excessive list prices).

Because no clear rationale has been provided for this latest set of changes, GSK and other stakeholders may be left with the impression that this reversal is simply a knee-jerk reaction by the Board to the government's validly enacted regulatory implementation delays resulting from the COVID-19 pandemic.

A Pathway Forward for Canada

Consistent with the approach that GSK has taken throughout this 5-year consultation process, GSK is offering a couple of alternative policy approaches for the Board's consideration, which would deliver on the PMPRB's stated objective of implementing the new pricing regime on July 1, 2022 without further delay. These alternatives would also mitigate the grossly overburdened financial consequences for GSK and other manufacturers, arising from the new pricing test for Grandfathered drugs that is now under discussion.

For example, has the Board considered whether a request could be made of patentees to submit their Block 5 data of the PMPRB11 prior to January 1, 2022 for grandfathered medicines on a good-faith basis? Under the circumstances, if they were asked, perhaps a critical mass of patentees would be willing to comply with such a request if the Board were to signal an intention of reverting to HIP PMPRB11 as the pricing test for Grandfathered medicines.

Hypothetically speaking, obtaining Block 5 data of PMPRB11 before January 1, 2022 would give the PMPRB advanced time to begin the calculation process of MLPs for grandfathered medicines and provide these said MLPs to patentees. This would in-turn provide patentees with a very stringent but potentially manageable timeline to implement price changes.

Another pathway for the Board to consider is widening the prospectus for reassessment. The PMPRB could theoretically provide patentees with MLPs based on MIP PMPRB7. However, if the resulting MLP is found to have caused undue impact, patentees could file for reassessment. The current standing reassessment criteria would be altered to account for instances where the application of the MIP PMPRB7 price test grossly impacted a patented product, in a manner that was not intended by the PMPRB reform. The specific threshold and criteria for reassessment would then be a topic of further consultation should the Board elect to pursue this alternate route.

Perhaps if such steps were taken by the Board, it could allow for implementation in accordance with the near-term timeframe that the Board envisions, while also, delivering the drug costs savings that payers have presumably been expecting to realize through the October 2020 Guideline implementations. This could also be an important first step in allowing all parties to move forward from what has been a very challenging time for those on all sides of this debate, returning to our shared goals of protecting and promoting the health of Canadians and building Canada's life sciences sector.

Yours truly,

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