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

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

August 3, 2020

Douglas Clark
Executive Director
Patented Medicine Prices Review Board
1400 – 333 Laurier Avenue West
Ottawa, Ontario K1P 1C1

RE: GSK's Submission Regarding the June 2020 Proposed PMPRB Pricing Guidelines

Dear Mr. Clark:

On behalf of GlaxoSmithKline Inc. ("GSK"), I welcome the opportunity to provide you with feedback and recommendations regarding the June 2020 PMPRB Draft Guidelines.

I would begin by noting that GSK's key positions with respect to the June 2020 Draft Guidelines are substantively consistent with the input our company has provided in previous submissions (including our February 2020 submission which I attach as an appendix to this letter), and I would refer any readers of this letter to those earlier documents rather than reiterate our earlier comments at length.

As you know, GSK is a science-led global healthcare company tackling some of the world's most pressing health challenges. We have a proud history in Canada, dating back to 1902. GSK has leading positions in respiratory disease and HIV, as well as a robust pipeline of new medicines, including candidate oncology medicines and antibiotics. GSK also has one of the broadest vaccine portfolios in the world, helping to protect Canadians of all ages against vaccine-preventable diseases.

It is from this perspective that I provide GSK's overall impressions and observations regarding the June 2020 Draft Guidelines:

1. We note that the PMPRB has made adjustments based on the feedback provided in February 2020, including feedback from GSK, as well as patient groups and others.

2. However, GSK remains concerned about the overall direction of the reforms, and the impact the new Patented Medicines Regulations will have on Canadians' future access to innovative medicines, as well as on the country's ability to attract investment to our life-sciences sector.

In these difficult and uncertain times, the life sciences industry is vital to the health and well-being of all Canadians. Canada and Canadians need, and deserve a stable and predictable regulatory environment that encourages life sciences companies to grow and thrive.

3. The policy approach for tendered vaccines in the June 2020 Draft Guidelines is *slightly* better than the approach proposed in the 2019 Draft Guidelines, but there is still considerable room for improvement. Given the central importance of vaccines to the health of Canadians, and the fact that Canada already has a well-functioning public tendering system that fosters regular competition amongst manufacturers and acts as a *de facto* price control mechanism, GSK remains disappointed that no exemptions have been included for such products. The proposed carve-out of COVID-19 related products in the latest Guidelines is an acknowledgment of the unintended risk to supply posed by these new pricing rules, which do not reflect a predictable regulatory mechanism for vaccines and other tendered products.

4. It is a matter of public record that the innovative pharmaceutical industry is willing to help realize significant changes to drug pricing in Canada. Through continued collaboration and dialogue, GSK believes we can find constructive solutions on affordability, while meeting the legitimate business needs of manufacturers for predictability, and also ensuring robust access to innovation for patients.

If implemented without further substantive changes, the June 2020 Guidelines will have a significant and negative impact on new R&D and life sciences investment, vaccines supply, and patient access to new medicines in Canada. GSK's concerns and key recommendations are outlined in detail below.

Recommendation #1 – Do not apply Category I constructs (e.g. Market Size Adjustment and PE) to vaccines as these constructs are not appropriate / workable for tendered vaccines.

While the Board's decision to move the market size adjustment threshold for all new patented medicines from $25M to $50M in the June 2020 Guidelines – including vaccines – could be seen as positively intended, the continued presence of this adjustment at any threshold, when applied to vaccines, simply perpetuates pricing uncertainties to manufacturers, which in turn risks undermining the tendering process.

Most vaccines take many years to make and, as a result, global companies need to allocate stock years in advance based on a variety of different criteria, including measures such as country price. Given the uncertainty created by the continued presence of a market size adjustment – even at this higher threshold – manufacturers in some cases may only be able to secure a limited quantity of vaccines at a given price point. This could exacerbate market shortages down the road. With Canadians' demand for innovative vaccines only expected to grow over the coming years, the new pricing measures proposed by the PMPRB could put the security of Canada's vaccine supply at risk, and could needlessly undermine Canadians' access to vaccines, which are among the most cost-effective means of public health promotion and disease prevention available to federal, provincial and territorial health providers.

Moreover, we note that Grandfathered vaccines would not be subject to any market size adjustment whereas new-to-market vaccines with forecasted annual sales of over $50M would be subject to the adjustment. This dichotomy risks creating unfair market dynamics in a tender situation. Simply put, a vaccine manufacturer with a new vaccine would be competing head-to-head to win a given tender in an uneven playing field - against one or more manufacturers with older vaccines that would be playing under

different rules. This in turn could be a further disincentive to bring new vaccine technologies to the Canadian market.

The obvious solution to this and other problems with how the June 2020 Draft Guidelines propose to treat non-Grandfathered vaccines would be to follow the example set in the new Draft for a carve-out for biosimilar medicines. The PMPRB could readily create a similar carve out for new vaccines where Category I constructs, such as PE and Market Size, are not applied.

In considering this proposal for a lighter regulatory touch, one should keep in mind that in December of 2017, Health Canada published for public consultation a draft set of amendments to the Patented Medicines Regulations published in the Canada Gazette. Those draft amendments included provisions specific to vaccines, which laudably proposed to modernize and simplify the way that vaccines are regulated by the PMPRB. Specifically, it was proposed that vaccines would be subjected to a different regulatory approach than patented drugs and biologics in recognition of the fact that, in the language used by Health Canada, vaccines have a "low risk of potential abuse of statutory monopoly."

The approach proposed by Health Canada in 2017 made a great deal of sense at the time – and still makes sense today – because vaccine procurement in Canada is based on a competitive tendering process, whereby the lowest bidder is granted a majority share of the contract to supply the customer with a specific vaccine. This national tendering system ensures that patented vaccines are fairly priced within the Canadian marketplace. Moreover, the provinces and territories that leverage the federal tendering process to secure vaccines for their populations are sophisticated actors, and they have the purchasing power to negotiate contracts that provide optimal arrangements in terms of price, quality and volume.

Recommendation #2 – If NEAP is to be used as a pricing tool in the case of Grandfathered vaccines, more clarity is needed on how it would be applied in the case of public tenders.

The proposed Guidelines state that MLP for all Grandfathered patented medicines, including vaccines, would be set at the lower of the highest international price ("HIP") for the PMPRB11 countries for which the patentee has provided information or the patented medicine's ceiling (e.g. the "NEAP") under the Guidelines applicable prior to the issuance of these Guidelines. GSK disagrees that the NEAP from any given year should be used to set the MLP for a Grandfathered vaccine. If NEAP is used to set the MLP for Grandfathered vaccines, in the case of new public contracts going forward, GSK may either be unable to offer discounts of the nature that provinces/territories have historically come to expect, or be unable to secure doses for public tenders resulting in no bid. This is because NEAP would set a maximum list price based on average transaction prices, which effectively penalizes manufacturers for the discounts provided to provinces via the tendering process (i.e. in a global context, where Canadian list prices are referenced by other countries, this may compromise manufacturers' ability to offer discounts).

By adding the new Section 76 to the proposed June 2020 Guidelines, the PMPRB appears to be acknowledging that using NEAP as a price-setting tool may be problematic. Under Section 76, manufacturers seem to be afforded an opportunity to engage with PMPRB staff in specific instances where the published list price of a patented medicine would be negatively impacted by the reporting of benefits such as price discounts, and request relief from such impacts if there is evidence that the calculation of the NEAP of the vaccine in question is "uncharacteristically low" due to the reporting of such benefits. This is a good first step, but Section 76 needs to go further. Even with the addition of this section, there remains considerable price uncertainty as Section 76 can only be invoked *after* MLP has been set. To date, there has been little guidance provided on how this new section will be operationalized (i.e. criteria to form a "bright line" test on what, exactly, constitutes "uncharacteristically low"). The

absence of such criteria means that manufacturers in some cases may not be able to offer price/volume discounts to public payers where doing so would create uncertainty around the list price, which in turn would impact availability of vaccines to Canadians.

Moreover, it seems certain that the proposed use of NEAP to calibrate the MLP for Grandfathered vaccines is also likely to result in a significant increase in submissions by industry (under Section 76) and workload for PMPRB as it will trigger reviews across a wide range of products for multiple patentees. Assuming the Board's policy intent in adding this clause has to do with safeguarding Canada's public vaccines supply, while ensuring that provinces continue to enjoy discounted prices via tendering, GSK firmly believes the Board could achieve this same policy objective with considerably less administrative burden for manufacturers – as well as for its own staff – by doing away with the NEAP rule altogether.

Finally, the June 2020 Guidelines would reduce the likelihood that a global manufacturer would launch a new vaccine in Canada first, ahead of other PMPRB11 countries due to one important but correctable issue. Under the proposed rules, if a vaccine is launched first in Canada out of PMPRB11, the product's interim MLP (iMLP) will be set at domestic therapeutic class comparison, which relies on Canadian vaccine prices that are already among the lowest in the OECD. Historically, it is rare for Canada to be the first launch country, but it is not unheard of. In fact, one of GSK's latest vaccines was first to launch in Canada, well ahead of other PMPRB11 countries. This simply would not happen under the proposed new rules. The dTCC is not an appropriate threshold to set the iMLP for innovative vaccines if the goal is to attract such innovations to Canada, and an alternative approach that is grounded in the Basket is needed.

Recommendation #3– Put the current Guidelines consultation on pause, establish in its place a technical working group with the industry, and work together to produce a more feasible approach to regulating high cost drugs that is consistent with the principles of fairness and predictability.

GSK notes that the current draft of the PMPRB Guidelines continues to advance the concept of a Maximum Rebated Price (MRP, which reflects the inclusion of third-party payments that are beyond the PMPRB's jurisdiction). On June 29, 2020 the Federal Court ruled that sections of the August 21, 2019 amendments to the Patented Medicines Regulations in relation to confidential third-party payments were ultra vires of the *Patent Act*. The MRP-related proposals in the June 2020 Draft and earlier draft Guidelines proposals are clearly based on having access to this ultra vires information.

Given that this maximum rebated price concept is so central to the proposed Guidelines approach, GSK fundamentally disagrees with the PMPRB's July 8, 2020 e-mailed statement to patentees that it "does not believe any substantive changes to the June 2020 Draft Guidelines are required." This statement by the PMPRB seems out of sync, because without access to third-party rebates, the PMPRB would seem very challenged to implement the MRP concept.

We recognize and acknowledge the "softening" that has now been proposed in the June 2020 Draft Guidelines regarding the application of the so-called "new economic factors," including the much higher QALY thresholds. But our fundamental concern with the factors remains unchanged. Regardless of the QALY thresholds used, the new factors do not allow for reliable prediction of an allowable ceiling price at product launch, or throughout a normal product lifecycle, due to their inherent subjectivity, as well as the broad criteria for reassessments after products are launched. Again, GSK recognizes the role that Pharmacoeconomics can play in certain circumstances, such as informing value-based discussions with HTA bodies. But we disagree strongly with the notion that PE tools should be used to help establish a regulated price ceiling – at least not on a routine basis.

The subjectivity of the new economic factors creates tremendous unpredictability in the Canadian pricing regime, and we are already observing an impact on global launch decisions across the industry. In a recent study, commissioned by Life Sciences Ontario by IQVIA, "New Medicine Launches: Canada in a Global Context", a deep dive into comparing Canada to international markets in terms of time to launch, proportion of launches and sequence in launch for new medicines was conducted. The study showed that while Canada saw a steady climb of new active substances being launched in Canada over most of the study period (2005-2019), annual new drug launches in Canada dropped significantly in 2019.

This is in direct contrast with the global market where launches were on the rise in 2019. For example, in Canada in 2019, there were 13 new drug launches compared to 35 new drug launches in the US. IQVIA looked deeper into the therapeutic areas and it was noted that most of the medications were in Oncology and the rare disease area, which typically would be considered high cost medicines. It is important to note that the number of patients who need Oncology drugs are increasing in Canada. Last reported in 2018, 1.8% of Canadians used an oncology drug, up from 1.65% in 2017 and 1.1% in 2008.

Given the emerging launch trends we are seeing, coupled with the recent federal court ruling, and also given the highly uncertain and in many ways unprecedented times we currently find ourselves in, GSK strongly encourages the PMPRB to reset its overall approach to Guidelines modernization. As a country, we can take a more cautious, and also more consultative, path forward.

The case for proceeding with caution around an overhaul of Canada's longstanding drug pricing regime, at a time when the nation's drug supply as a whole has been shown to be at risk due to stiffening borders, is made all the more stark when one considers the fact that drug prices in Canada are barely even rising.

According to the PMPRB's own data, there is clearly no "affordability crisis" when it comes to the prices of patented medicines in this country. GSK fully acknowledges 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. We also recognize that industry has a necessary and important role to play in coming to the table with ideas and solutions. But when we look out the window today, it is clear from the data that "the sky is not falling" when it comes to affordability. In fact, the domestic price trends in the PMPRB's recently published 2018 annual report show that prices of patented drugs increased by less than 1% in 2018 on the basis of list prices, and actually *decreased* on a net price basis when confidential rebates are factored in. Moreover, the 2018 list prices were lower than introductory prices for drugs introduced every year since 2009.

Given these trends, where Canadian drug prices remain quite stable over time and are not growing at an unsustainable rate, and given the recent federal court decision, it is hard not to wonder if these pricing reforms should not unfold over a more reasonable time horizon. Either way, GSK will continue to welcome any and all opportunities to engage with PMPRB to collaboratively generate a set of pricing rules that address the key principles of predictability, fairness, operational feasibility, and most fundamentally, continued access to new medicines for Canadians to a high global standard.

Yours truly,

Yoo-Seok Hong
President & GM, Canada Pharmaceuticals
GlaxoSmithKline Inc.