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July 18, 2021

Dr. Melanie Bourassa Forcier
Interim 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 – PMPRB Price Review Approach During the Interim Period following publication of Amendments to the *Patented Medicines Regulations*

Dear Dr. Forcier:

GSK is a science-led global healthcare company tackling some of the world's most pressing health challenges. We have leading positions in respiratory disease and HIV, as well as a robust pipeline of new medicines, including candidate oncology medicines and novel antibiotics. GSK also has the broadest vaccines portfolio of any company in the world.

GSK has a proud history in Canada, dating back to 1902. Over time, GSK has grown to have one of the largest economic footprints of any multi-national pharmaceutical company in Canada, with manufacturing facilities in both Ontario and Quebec. Currently, GSK employs 2,500 employees across the country and GSK is also among the top investors in research and development in Canada. We have invested more than $2 billion since 2001 in Canadian pharmaceutical and vaccines Research & Development (R&D), with 60 million in 2020 alone. In 2020, we invested over $9.1 million into 32 active clinical trials across Canada involving 1,303 active subjects.

GSK has always sought opportunities to engage in good-faith, solutions-oriented dialogue with policy and guidance-makers on how to address affordability and sustainability in Canada's pharmaceutical system. In line with this, GSK is pleased with the federal government's decision to amend the patented medicines regulations by removing the detrimental pharmacoeconomic factors and market size adjustments. These actions are a positive step to ensuring predictability within the Canadian market and creating an environment conducive to launching new, innovative medicines and vaccines. We would also like to thank the Board for the opportunity to provide feedback in response to the Interim Guidance published on June 30, 2022.

GSK has no substantive comment specifically on the interim guidance, however as the board reflects on potential elements in the development of proposed final guidelines, we would like to take this opportunity to build on previous communications GSK has had with the PMPRB. From the outset of the PMPRB reforms in 2017, a consistent concern for GSK and the industry more broadly has been related to the lack of certainty and the impact it has on our ability to plan. As such, we would like to reiterate the

critical importance of predictability within the guideline implementation of these new regulations to support long-term planning.

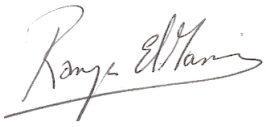
GSK has reflected on the pricing tests that we believe appropriately encompass value, cost and innovation through our numerous consultation submissions which you can find in the attached appendix. It remains clear that delineating between MIP and HIP for new and grandfathered medicines is critical to preserving the viability of these medicines.

Additionally, we took notice to the fact that the interim guidance does not speak to the “grandfathering” of existing medicines. We have taken signals from the Government and PMPRB about how grandfathering should be approached, based on the 2019 Cost-Benefit Analysis. Given the weight provided to this CBA both by government and the PMPRB, GSK has integrated these assumptions into financial planning, investment decisions, and launch decisions, and would expect predictability in this regard in the Final Guidelines. The concept of grandfathering spans beyond this particular case and is a widely utilized method of implementing any sort of reform. It is also worth noting that a report from the Office of the Parliamentary Budget Officer compared expenditures at PMPRB7 HIP prices versus PMPRB11 HIP prices and found that expenditures are expected to be 57% lower under PMPRB11 HIP prices. This represents significant cost savings to consumers and programs without any additional price reduction pressures causing undue impact to the business.

Acknowledging reference to changes to CPI in the *Patent Act* as it pertains to pharmaceutical prices, GSK believes that the PMPRB’s longstanding price increase methodology is a tried and tested implementation of the regulations. This method of allowing price increases based on a three-year lagged CPI has been instrumental in embedding provisions that allow drug pricing to balance changes in market dynamics while also ensuring that consumers and patients are protected during times of high inflation. GSK recognizes that the PMPRB is making decisions about an appropriate price increase methodology in the context of a high inflation environment, and appreciates the careful consideration required for an issue at the forefront of all aspects of life for Canadians with impacts spanning across, patients, industry, stakeholders, and the economy.

Thank you again to the Board for this opportunity to provide feedback. We look forward to the release of the Final Guidelines and urge the board to reach out at any time to develop meaningful discussions as it pertains to the development of the guidelines. GSK welcomes all further related opportunities to engage and ensure continued access of innovative medicines for all Canadians.

Yours truly,



Ranya El-Masri
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August 31, 2021

Dr. Mitchell Levine
Chair of the Board
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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
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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.