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Mr. Doug Clark
Executive Director, Patented Medicines Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear Mr. Clark,

Re: PMPRB Guidelines Modernization

GlaxoSmithKline appreciates the opportunity to share our perspective as part of the Patented Medicines Pricing Review Board's (PMPRB) public consultation regarding possible reforms to its "Compendium of Policies, Guidelines and Procedures". As an innovative pharmaceutical company, we are committed to achieving a sustainable healthcare environment for all Canadians and welcome an open dialogue with the appropriate stakeholders to ensure that Canadians benefit from the innovative medicines being brought to market.

As part of this consultation process, we are submitting our response to the changes and discussion points presented by the PMPRB in order to facilitate further discussion as the process moves forward. We respectfully submit that the PMPRB has done its job to date of ensuring that the prices of patented medicines in Canada are not excessive and the focus of this mandate should be retained, in light of the broader elements of the Canadian system. That being said there are opportunities for PMPRB to further sharpen its focus to eliminate redundancy and improve impact.

In 1987, Parliament recognized the need to restore the patent protection to pharmaceutical manufacturers in Canada which had been lost years earlier through compulsory licensing. This elimination of compulsory licensing was required in light of Canada's voluntarily-assumed international trade obligations under North American Free Trade Agreement (NAFTA) and Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement as they related to fair and equitable treatment of all industries under patent laws. This reform was intended to return Canada to a relatively level playing field compared to other developed nations, and to recognize innovation. In this vein, the PMPRB was established to ensure that the prices of patented medicines sold in Canada did not become excessive by global standards. Since its inception, PMPRB has succeeded in its original mandate by maintaining the average Canadian patented drug price below the median international price since 1994.[1] Indeed in 2015,

[1] Patentee Medicines Prices Review Board, Annual Report, 2003, 2015

Canadian drug prices were on average 18% below median international price – the highest difference in over 15 years.[2]

Addressing the Mandate Change:

To argue, as the discussion paper attempts to, that this mandate needs to be "modernized" to ensure that prescription drug prices in Canada are "affordable" from a consumer protection perspective appears on the surface to be a reasonable position. However, such an argument ignores not only the established purpose of the PMPRB, but the broader ecosystem which currently regulates prices of patented medicines in the Canadian market. It also has the potential of interfering in areas such as determination of value and affordability which are the clear mandate of other bodies (specifically the Canadian Agency for Drugs and Technologies in Health (CADTH), the Institut national d'excellence en santé et en services Sociaux (INESSS) and pan-Canadian Pharmaceutical Alliance (pCPA)). These organizations did not exist at the time PMPRB was established but developed in the ensuing years to fill those gaps in the Canadian pharmaceutical system. Admittedly this system may not work perfectly, and there is much room for reform but, nonetheless, GSK submits that intervening and overstepping mandates, without regard for the unintended consequences or impact to the broader ecosystem, is a dangerous precedent. Furthermore, for PMPRB to move from preventing "excessive" prices to ensuring "affordable" prices requires legislative changes to both the Patent Act and associated regime. As currently drafted, the Patent Act mandates that PMPRB consider all of the factors listed in section 85 of the Act when assessing what is "excessive". The Patent Act does not support an assessment that is based upon ability of a customer to pay. Any attempt to change only the regulations or guidelines is not consistent with the core concept that the regime must take into account the very Act on which it was founded.

Furthermore, the regulation of pricing by PMPRB must respect the scope of PMPRB's power and not infringe upon the division of powers in the Constitution Act. PMPRB has jurisdiction over factory-gate pricing; however its constitutional limitations do not permit interference with contractual arrangements involving patentees and entities further down the drug distribution chain. Introduction of an assessment of whether a customer can "afford" a medicine appears to be unconstitutional on this basis, in addition to being inherently incapable of transparent and rational analysis.

This is not to say that the affordability of innovative pharmaceuticals is not an important issue - it is. However, the solution does not lie in simply taking a single "cost" based approach; rather, affordability depends on a consideration of value to the patient, system, and society. The PMPRB is not in a position to assess this as its data, tools and expertise are designed to monitor and regulate prices based on those in comparative countries. It is the role of other agencies in our current system to ensure we optimize value (HTA) within the scope of current budgets (pCPA). From an affordability perspective, the pCPA together with the pharmaceutical industry have entered into negotiations. These have generated savings which are currently tracking at $712M annually[3] over and above the "non-excessive" prices established by PMPRB. This represents a savings of approximately 5.7 % of total public sector spend on prescribed medication to date and is growing rapidly (almost 40% increase in savings versus the previous

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[2] Patented Medicines Prices Review Board, Annual Report, 2015.

[3] The pan-Canadian Pharmaceutical Alliance, Canada's Premiers, 2016. http://canadaspremiers.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance

year). Furthermore private payers, for whom pharmaceuticals provide a different and distinct value proposition, have always had the ability to generate further savings and in recent years, they have actually begun to develop and utilize their own tools to ensure affordability to their members. These facts demonstrate that the ecosystem is working – albeit not perfectly.

As a company, we acknowledge that, despite the combined efforts of government, regulatory bodies and pharmaceutical companies, some Canadians struggle with affordability due to inadequate levels of drug coverage – they are either uninsured or underinsured. These individuals are generally those who bear the burden of paying the cost of their medicines out-of-pocket or having to do without. As a company whose core value is putting patients first, we recognize that this is an area of great concern and are committed to working on a solution to this problem with the relevant stakeholders. However, this issue is not solely an issue for PMPRB and cannot be solved through unilateral changes to one regulatory body.

Addressing Therapeutic Benefit:

In its discussion paper, PMPRB has suggested that categorizing medicines based on perceived therapeutic benefit is "not aligned with PMPRB's mandate of balancing monopoly power held by the patentee of a medicine". We strongly disagree with that suggestion since one of the foundational elements of determining the ceiling price of an innovative patented medicine is the level of therapeutic benefit it provides. Further to this point, therapeutic contribution is highlighted in two of the factors to be considered by PMPRB in determining excessive price. Removing it from the assessment would be inconsistent with the statutory scheme. The inclusion of therapeutic class as a limitation for comparisons with other products is a clear indication that Parliament views therapeutic value as an important factor in determining whether a medicine is marketed at an excessive price. Consequently the position espoused in the discussion paper counters the premise of the Act on which the guidelines are based and further ignores the very fact that medicines, at their core, are not commodities but rather innovations designed to improve health. With innovation comes improvement, and the greater the improvement the greater should be the recognition. To reiterate, the Patent Act exists to recognize innovation not to penalize it. PMPRB's role may not be to recognize innovation in itself, but it is a body created under the Patent Act and its mandate must be interpreted in light of, and respect the very purpose of incentivizing innovation. The current PMPRB mandate and its Guidelines appropriately recognize the therapeutic contributions of innovative medicines by setting a scaled ceiling price based on the level of benefit while ensuring the appropriate price controls are in place. This is reasonable, and in accordance with the overarching objective of the Act; it must be maintained as an essential element of our system.

Addressing Outliers:

The Canadian pharmaceutical market grew approximately 6.2% in 2015 but a deeper analysis demonstrates that with the exception of four specific hepatitis C products (Sovaldi, Harvoni, Galexos and Holkira Pak), the annual growth rate in 2015 was only 3.8%.[4] Thus these four products, out of over 4000 prescription medicines in Canada, can account for almost 50% of this reported growth, and may be the root cause of an unnecessary "knee-jerk" reaction. Indeed these therapies have provided remarkable outcomes, even curative, resulting in benefits to the patient and significant downstream savings to the

[4] IMS Brogan, Canadian Drug Stores and Hospital Purchases, 2015.

healthcare ecosystem. Nonetheless products of this nature, despite best efforts by PMPRB to ensure non-excessive pricing and the significant benefit they provide, might still be considered too expensive for payers to afford particularly using current payment schemes. However, to reengineer the whole system which is working well, for the sake of a very few select products makes little sense rather; it would make more sense to develop a process for dealing with the specific drugs (i.e. ring-fencing). In many cases breakthrough innovations are life saving treatments and, if this is valued by the system, they should receive the highest price premium permissible. Then following PMPRB's establishment of non-excessive price, payers and manufacturers should work together to find innovative ways to address affordability which appropriately reflect the value the product brings to patients and the payer system (i.e. pay-for-performance, amortized payments, system trade-offs, etc.). It is not the role of the PMPRB to enter into affordability models or payment schemes. Affordability is subjective and decisions regarding budgeting and expenditures are best determined by the payers who are accountable to their constituents and who can appropriately make value-based assessments. The function of the PMPRB is to ensure that the price of a medicine is not excessive relative to global comparators, and special attention should be made to address outliers directly.

Furthermore, over 80% of the products reviewed by PMPRB are assigned to the "little to no improvement" therapeutic category (84.2% in 2015[5]). Nonetheless these products are still important because they provide patient choice and often bring incremental improvement which drives further innovation. However, it is clear from this assessment that PMPRB believes there are available alternatives in the market. Alternatives would imply there is already competition and if there is healthy competition, then regulated price control and the associated administrative burden it causes are not necessary. This may be an opportunity for PMPRB to further focus its energies and enhance its impact on the outliers.

Addressing Tendered Vaccines:

One other area where PMPRB might consider focusing improvements is in the pricing controls imposed on publicly funded vaccines. With respect to vaccines that are publicly procured, provincial and federal payers combine to tender for these products to create a unique set of market forces. In Canada, the tendering process provides government payers a significant amount of control over prices and aids in the establishment of a healthy and competitive price point. However, because the production of vaccines is more complex, it can at times result in unpredictable and constrained global supplies. When vaccine supply is restricted, its global allocation naturally becomes price-related. In these situations, regardless of the willingness of Canadian payers to pay a premium for these vaccines, procurement may not be permitted due to the established price cap set by PMPRB. In reality, PMPRB's intervention does not serve any relevant purpose in this space, rather it creates unnecessary administrative burden (due to resulting investigations) and has potential for limiting or preventing supply of vaccines to Canadian patients.

In the event the tendering process is unable to constrain prices (i.e., sole provider of a technology), the Public Health Agency of Canada (PHAC) has a process designed to leverage the Comité sur L'immunisation de Québec (CIQ) and the National Advisory Committee on Immunization (NACI) and their economic evaluations (NACI+) which are independent and capable of establishing specific ceiling prices without placing supply or allocation at risk. Consequently, with respect to publicly

[5] PMPRB Annual Report, 2015

tendered vaccines, PMPRB presence is not only unnecessary but actually counter-productive and may contribute to supply issues and thus public health issues for Canadian patients.

Addressing Regulatory Scope for Vaccines:

Vaccines are often built on platforms that could be used across several different products. Patents that cover some of the building blocks of these platforms often pertain to several or even all of a manufacturer's vaccine products. Under the current application of the "merest slender thread test", manufacturers are required to report many patents that provide no product-specific protection and therefore have no relevance in pricing of these products. The "merest slender thread test" and its application result in unnecessary administrative burden to both the PMPRB staff and manufacturers. This is an area in which PMPRB could re-evaluate in its modernization process.

Addressing R&D Investment:

In addition to the primary mandate of ensuring innovative medicine prices are not excessive, the PMPRB has a secondary mandate of "monitoring and reporting on pharmaceutical trends and R&D spending by patentees." In 1992, the pharmaceutical industry committed to investing in Canada through enhanced R&D investments equal to 10% of its annual sales. This was never required by law, time-bound, nor linked to the price of pharmaceuticals. Rather it was simply recognition of the significant improvement in the investment climate as a result of returning to globally competitive patent protection. To be clear, this commitment was not a *quid pro quo* for the abolishment of compulsory licensing – as noted above, Canada had to repeal that regime to meet its international trade obligations.

In 1998, the Auditor General of Canada concluded that the industry had consistently met its commitment and questioned the relevance of continued monitoring and reporting by PMPRB. However, no changes ensued and PMPRB continued to "hold" the industry to this old standard and outdated definition of R&D despite the deteriorating investment and intellectual property climate in Canada. Consequently PMPRB has reported that industry contribution declined year over year since the late 1990s and this is used as an argument why Canadian prices need to be lowered. PMPRB's assertion that industry is not investing is challenged by a 2014 report by KPMG[6]. It identified that, when using a more current and relevant definition of R&D (including Scientific Research and Experimental Development (SR&ED) eligible and non-eligible investments), the industry actually invested almost 50% more in R&D in 2014 than what was reported by PMPRB ($699M vs. $1.02B) and the sum total of all investment by the pharmaceutical industry in Canada was almost double that ($699M vs. $1.28B). The purpose of presenting these data here is not to argue facts and figures, but to highlight the value the pharmaceutical industry continues to bring to Canada. These investments are made, not because of a need to comply with any commitment but because the pharmaceutical industry sees value in investing in Canada.

While there may not be a direct link between price and investment, there is a direct link between investment and economic growth. Canada, on the strength of the pharmaceutical industry, has seen the growth of a healthy and globally recognized clinical research capacity and a burgeoning Life Sciences sector. Therefore, rather than using an arbitrary measure of R&D investment as a "stick" to point out that

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[6] http://innovativemedicines.ca/wp-content/uploads/2015/05/2014-06-20_RxD_RD_Report_FINAL_EN.pdf

the Canadian industry is not meeting an outdated commitment; the actual investments should be reported and encouraged as part of our nation's commitment to Life Sciences and the broader knowledge-based economy. The Patent Act exists to encourage innovation, so while monitoring and reporting should continue, the definition of R&D should be "modernized" and the actual contributions celebrated and encouraged. This initiative may receive greater value and recognition from Canadians themselves by being placed in the purview of another government department/agency rather than a one focused on price control.

Conclusion:

PMPRB, with their legislated mandate, has played a historically relevant role in Canada for the better part of three decades. This role and mandate are no less important today. What has changed since the inception of PMPRB is the evolution of the Canadian ecosystem which now includes active HTA and payer components; each of which plays an integral and integrated role in ensuring that Canadians get the medicines they need, at prices they can afford and which are internationally comparable. For this reason, we believe the current PMPRB mandate to control excessive drug prices, as set out in the Patent Act, is appropriate and should only be modernized insofar as to allow it to work more seamlessly within the broader ecosystem. PMPRB can achieve this by understanding and respecting the boundaries of its mandate and working within them to eliminate inefficiencies and enhance its impact. Restrictions on access to innovative products will be an unintended consequence of PMPRB reform if this process is not fully considered.

We all need to be stewards of healthcare in Canada. This is our system; it works but we acknowledge it has flaws that require integrated solutions, and as Canadians we stand ready to be a part of those solutions. We reiterate our appreciation for the opportunity to share our perspective on the PMPRB discussion paper and welcome the next steps as the consultation process continues.

Sincerely,

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General Counsel