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Mélanie Bourassa-Forcier
Vice-Chair
Patented Medicines Prices Review Board
1400 – 333 Laurier Avenue West
Ottawa, ON K1P 1C1

RE: PMPRB Notice and Comment – Draft Guidelines

Dear Ms. Bourassa-Forcier

I am writing on behalf of GSK Canada to share our comments regarding the proposed Final Guidelines and the associated transition process.

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. 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 one of the broadest vaccines portfolios of any company in the world.

GSK's history in Canada dates 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 offices in Montreal and Mississauga, and a vaccines manufacturing plant in Quebec. GSK employs over 1,700 employees across the country, and we are also consistently among the top investors in R&D in Canada. We have invested more than $2 billion since 2001 in Canadian pharmaceutical and vaccines R&D, with $60 million invested in 2020 alone. Finally, I note that an independent 2021 economic impact study by KPMG showed that GSK also contributes $194 million every year to Canada's GDP.

With immense pride in our Canadian heritage, we are guided by our ambitions for Canadian patients and seek opportunities to engage in solutions-oriented dialogue with policy makers on how to strengthen Canada's pharmaceutical system. We're proud to have taken every opportunity to participate in the ongoing pricing reform consultations dating back to 2017, including this latest round of consultation.

It must be acknowledged that “the sky is not falling” in Canada when it comes to the affordability of patented medicines (i.e. the domestic price trends in the PMPRB’s 2021 annual report show that the national average transaction price for patented medicines increased by just 0.4%, while the Consumer Price Index rose by 3.4% over the same period; and actually, prices might very well be decreasing on a net price basis when confidential rebates are factored in). But GSK does recognize that industry has a necessary and key 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.

With this context in mind, GSK acknowledges the Board’s consideration of earlier stakeholder feedback – specifically on the latest proposed approach in the Final Guidelines to existing medicines, as well as the approach to innovative vaccines, and the transition process.

Since the federal government first issued its new regulations in August 2019, GSK has expressed how critical it is for the guidelines to delineate between new and grandfathered medicines to ensure an appropriate degree of planning and predictability for Canadian innovative pharmaceutical companies, while staying true to the government’s policy objectives of affordability. We see that this feedback has sensibly informed the PMPRB’s proposed approach to existing products, including the application of HIP (Highest International Price) using the the PMPRB11 basket as the investigation trigger. This approach will generate immediate savings for provinces and cash paying patients alike.

GSK also welcomes the practical regulatory approach proposed for publicly tendered vaccines, specifically by employing a novel complaint-based process for vaccines. This recognizes that affordability for vaccines is well addressed by Canada’s established public tendering process. A complaint-based approach has the potential to reduce unnecessary administrative burden.

Finally, GSK acknowledges that the PMPRB has clearly heard and integrated concerns shared by GSK (and others) on the administrative unworkability of a transition period that is unduly short. The proposal for providing two reporting periods is workable from our perspective.

All this said, the draft guidelines as written will still have a significant negative impact, threatening the availability of new medicines and investment in R&D in Canada. Some of the elements proposed pertaining to new medicines may extend beyond the PMPRB’s legislated mandate to protect consumers from

excessive prices for patented medicines. By design, these provisions, at face-value, appear as though they may be intended to create downward pressure on prices. The baked-in unpredictability of a “rolling dTCC” with each new indication might inadvertently deter the launch of new indications in Canada, particularly for drugs with relatively small patient populations (e.g. drugs for rare diseases).

Throughout this pricing reform process, a recurring theme in the response from GSK and other stakeholders has been the need for *predictability* to enable long-term planning and to allow innovative therapies continue to be made available to Canadians early in the global launch sequence. In other words, governments and industry need to work together to ensure that Canadians continue to benefit from world class access to innovative drugs and vaccines. Yet, as with previous iterations of the proposed Guidelines, the persistent uncertainty as it pertains to new medicines remains a significant concern.

For example, rather than the “bright line” pricing tests that allowed patentees to discern, in advance, with a reasonable degree of certainty, the price that could be charged in Canada, the proposed Guidelines provide only a set of investigation triggers. For new products, these triggers require that the prices be below both the international median and the highest price in the domestic therapeutic class, suggesting that, on average, prices of new drugs in Canada must be lower than the median of the new lower priced basket of drugs to avoid investigation. In particular, in cases where the innovative new medicine is replacing old low-cost technology. This approach does not enable patent holders to determine non-excessive price thresholds and proactively ensure compliance, which creates business uncertainty.

Furthermore, if an investigation is triggered, under the new proposed approach, it appears that PMPRB staff would not be bound by any transparent rules, nor would they be guided by any set of explicitly stated principles as they have been in the past. This would result in a “black box” process that potentially enables the development and application of “bespoke pricing tests” (i.e. on a case-by-case basis at the discretion of PMPRB staff).

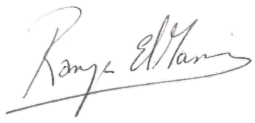
Bespoke pricing tests would mark a significant departure from decades of experience in Canada. Indeed, in the PMPRB’s very first Bulletin published in July 1988, its *Guiding Principles* stated that the most effective way to protect the public from excessive prices is to “rely primarily on voluntary action by patentees.” The Bulletin continued by noting that the Board believes that voluntary compliance can best be achieved by “clear,

understandable guidelines that provide, to the maximum extent possible, certainty and predictability for patentees in the definition of excessive price."

Some 30 years later, the Compendium of Policies, Guidelines and Procedures in effect up until recently has the following first line in the Preamble section: "The Patented Medicine Prices Review Board (PMPRB) is committed to making the price review process more open and transparent to all stakeholders."[1] In GSK's opinion, the Board's proposed approach to new medicines in these latest Guidelines runs contrary to these longstanding principles, creating an investigation process for drug review that is neither transparent nor open for stakeholders. GSK struggles to understand how this approach is achieving more effective price review, than the voluntary compliance achieved by clear understandable guidelines.

Given the outstanding concerns mentioned above, Innovative Medicines Canada has called on the PMPRB to suspend the current consultation and take a fundamentally different path forward. If the Board determines that the implementation of final Guidelines is to be further delayed, GSK believes it would be imperative that the approach to existing medicines remains as proposed in this latest draft, and further that the grandfathering date for existing medicines be recalibrated to account for any further extensions to the consultation process to avoid any negative impact on industry's ability to maintain significant levels of R&D and clinical trials investment in Canada.

As always, GSK remains prepared to meet with the PMPRB at any time to discuss any of the matters raised in this submission, and to provide further information. Thank you for the opportunity to provide feedback.



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[1] http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492#1633