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VIA the online submission portal

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Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Subject: MERCK PMPRB GMEP submission

On behalf of Merck Canada Inc. (Merck), thank you for the opportunity to provide comments on the PMPRB's proposed Guideline Monitoring and Evaluation Plan (GMEP). Our submission aims to complement those made by our industry associations, Innovative Medicines Canada and BIOTECanada.

We would like to start by noting that our participation in this consultation is not intended and should not be interpreted as supporting the amendments to the *Patented Medicines Regulations* or the PMPRB's Guidelines. Merck continues to have grave concerns about the practicality and legality of the amended Regulations, which are the subject of ongoing legal challenges, and which have most recently been challenged by the province of Quebec as being outside the scope of the federal government's jurisdiction.[1]

We also want to take this opportunity to re-emphasize our ongoing concern with how the PMPRB has conducted consultations with patentees and other stakeholders. Merck Canada and others have raised dozens of issues with the Guidelines and recommendations on how to improve them in order to provide greater clarity on how the regulations will be enforced.

At the start of the start of the reform process, the PMPRB committed to providing "bright lines" so that stakeholders can reasonably calculate prices that would be determined as in compliance with the PMPRB rules. We are now faced with Guidelines that will need to be enforced and worked through on a "case-by-case" basis, uncertainty with respect to how and in what circumstances a maximum-rebated price can or will be calculated and enforced and questions about how the new price tests will be applied.

In this context, Merck strongly believes that the proposed economic factors should not be used in a regulatory context and should be removed from the Regulations and Guidelines. These factors are incomprehensible and too subjective to provide the necessary level of predictability needed to commercialize medicines in Canada. They are the most problematic aspect of the reform and, along with plans to cap maximum public prices for innovative medicines at the

[1] Hill Times Research, Ontario and Quebec push back on PMPRB rule changes, June 2, 2021: https://hilltimesresearch.ca/ontario-and-quebec-push-back-on-pmprb-rule-changes/

effective median of the OECD, are already driving delayed new medicine launches and drops in research investments as shown in recent studies.[2] [3]

These issues have been exacerbated by the ongoing challenges related to the COVID pandemic. In this context, Merck and other stakeholders – including most recently the province of Ontario[4] – believe it is critically important to delay the implementation date of the Regulations, currently slated for July 1, 2021. This will allow additional time for discussion on the changes, while also supporting our sector's response to the crisis.

Against this background, we are pleased to provide the following considerations with respect to the PMPRB's proposed GMEP:

- **There is a need for a neutral third party to conduct the impact assessment**. There are many challenges with the PMPRB's proposed GMEP, the most important of which is the PMPRB's proposal to assess the impacts of its own regulatory activities. We believe that this evaluation should be carried out instead by a third independent party (e.g., Auditor General, CIHI, external consultancy, etc.). Given the recent publication of the PMPRB's communications plan[5] and internal exchanges among PMPRB staff displaying negative and biased views of the sector, we are even more concerned that the PMPRB will use selective data to justify its actions rather than evaluating the impacts of the changes objectively. More importantly, these recent revelations are very concerning for a quasi-judicial agency that is tasked with regulating prices in a fair an unbiased manner. Merck strongly believes that there should be an independent evaluation on the reforms before the changes come into force and a plan for independent assessment after any changes are made.

- **The GMEP consultation document includes misleading statements**: The discussion paper for the GMEP further reinforces our concerns about neutrality as there are several misleading / erroneous assertions with no sources or references in the document. For instance, page 6 of the document asserts that the PMPRB / Health Canada have been "borrowing the best practices observed in other developed countries for ensuring sustainable spending on pharmaceuticals and adapting them to the Canadian context," however no reference is provided to support this statement (no other country uses a quasi-judicial regulator with the power of law to drastically reduce the ceiling prices for new medicines across the entire market). In another example, the box text on page 9 alleges that drugs are now the second largest component of health spending (without

[2] IQVIA, June 22, 2020, New Medicine Launches: Canada in a Global Context: https://lifesciencesontario.ca/canada-may-be-losing-its-status-as-a-top-global-destination-for-new-medicine-launches/
[3] Research Etc, January 21, 2021, Health Canada Pricing Reform Research Report: https://lifesciencesontario.ca/wp-content/uploads/2021/01/Impact-of-Health-Canada-Pricing-Reform-FINAL-Report-Jan-21-2021.pdf
[4] Hill Times Research, Ontario and Quebec push back on PMPRB rule changes, June 2, 2021: https://hilltimesresearch.ca/ontario-and-quebec-push-back-on-pmprb-rule-changes/
[5] https://www.dropbox.com/s/eusxuabcq26uqt9/PMPRB%20ATIP%20Disclosure.pdf?dl=0

stripping away generics and over-the-counter drugs) and that Canadian spending per capita on patented medicines is second highest internationally (Canadian per-capita spending on drugs is significantly behind several other comparators). Again, the PMPRB appears to be selective in its framing to support its own regulatory approach.

- **The scope of the proposed GMEP is too large and complex**. It is impractical for any evaluator to attempt to track the dozens of factors listed in the GMEP. Instead, it would be more pragmatic and useful to focus on measuring a clear and small number of factors and metrics related to access to medicines, research investments (R&D) and jobs within the sector. This should not be an ongoing environmental analysis for the entire pharmaceutical regulatory, evaluation, negotiation and funding system.

- **The timeframe for monitoring the impacts needs to be appropriately determined.** The PMPRB's GMEP does not specify the baseline for assessing the impacts of the reforms. We should avoid using as a baseline the year immediately preceding the slated implementation of the reform (i.e., 2020-21), as this would skew the results given that the impacts of the PMPRB reform will have already been felt at that time. For this reason, Merck recommends that the impacts be evaluated from the start of the PMPRB modernization process, with the baseline of 2016/17. This is the date from which companies began to change their behaviour towards the Canadian market, in terms of medicine launches, research investments, and life sciences jobs.

In sum, we encourage the PMPRB to refocus its efforts on resolving the remaining issues in its Guidelines, while handing over the responsibility for measuring the impacts of the new rules to an independent third party.

Thank you for the opportunity to provide our comments. Please do not hesitate to contact me should you have any questions about this submission.

Sincerely,

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