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Patented Medicine Prices Review Board (PMPRB)
Box L40 | Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario, K1P 1C1

SUBJECT: NOTICE AND COMMENT INITIATIVE – PATENTED MEDICINES PRICE REVIEW BOARD - ON THE CHANGE TO THE DEFINITION OF GAP MEDICINES AND THE TIMELINE FOR COMPLIANCE

Dear PMPRB Board Members:

Thank you for the opportunity to provide comments on the changes proposed in this consultation. As noted by Health Canada, the delay in the implementation of the regulations was provided in the context of the COVID-19 pandemic to give patentees additional time to adjust to fundamental changes made to how the PMPRB operates. This delay, however, fails to address most of the concerns of Merck Canada Inc. ("Merck") and our industry associations, at a time when our sector is playing a critical role in developing and deploying therapeutics and vaccines that are central to the global and Canadian response to the crisis. Of most relevance for the purpose of this consultation, the delay granted by Health Canada would be effectively negated by the PMPRB's proposal to reduce the compliance period to one (1) reporting period (six months) from the current two (2) reporting periods (twelve months), and this is the main focus of our submission.

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 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 this 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. This situation has placed Canada at a disadvantage compared to other global markets, as there is no other global jurisdiction that regulates only patented medicines for their entire market to the same extent and level of uncertainty. As noted in BIOTECanada's submission, "new product launches will be focused on markets where this certainty is provided, and product value and price are evaluated collectively to help ensure the best use of therapies is serving patients who can truly benefit."

In this context, the current consultation is a missed opportunity to streamline how the PMPRB proposes to implement the Regulations. With respect to the specific proposal to reduce the compliance period, Merck strongly recommends that the PMPRB reconsider for the following reasons which are elaborated in more detail below:

- Patentees that are already strained by COVID-19 in terms of research and deployment of health technologies have vastly reduced capacity to modify and inform public and private payers of list price changes in a compressed period.
- Capacity and timing will also be challenges faced by the PMPRB staff who will have to liaise with manufacturers to determine evaluations for the non-excessive average price calculations.
- There are numerous benefits for retaining at least two (2) reporting periods that should be considered.

Here are the proposed changes outlined by the PMPRB in the notice and comment that Merck wishes to specifically address:

<table>
<tr><th>Change</th><th colspan="2">January 1, 2021 Guidelines</th><th colspan="2">July 1, 2021 Proposed Guidelines</th></tr>
<tr><td>Compliance Timelines with MLP</td><td colspan="2">76. Patentees must comply with the MLP within one (1) reporting period of the MLP being set for Line Extension medicines and within two (2) reporting periods for Grandfathered or Gap medicines.</td><td colspan="2">76. Patentees must comply with the MLP within one (1) reporting period of the MLP being set for Line Extension medicines and for Grandfathered or Gap medicines.</td></tr>
<tr><td rowspan="4">Compliance Timelines with MLP</td><td colspan="2">F. Summary of Compliance Timelines</td><td colspan="2">F. Summary of Compliance Timelines</td></tr>
<tr><td>Patented Medicine Category</td><td>Compliance Assessment</td><td>Patented Medicine Category</td><td>Compliance Assessment</td></tr>
<tr><td>Grandfathered</td><td>2 reporting periods</td><td>Grandfathered</td><td>1 reporting period</td></tr>
<tr><td>Gap</td><td>2 reporting periods (Dec. 2021)</td><td>Gap</td><td>1 reporting period (Dec. 2021)</td></tr>
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The change from two (2) reporting periods to one (1) reporting period cannot be taken lightly as it represents a significant change for all parties involved. Merck is strongly appealing to the PMPRB to maintain the existing wording of two (2) reporting periods as contained in the January 1, 2021 Guidelines.

Here are some of the considerations echoed by BIOTECanada and Innovative Medicines Canada:

1. Our company is still in the midst of COVID-19 related restrictions and so are many of our downstream stakeholders (provincial governments, hospitals, wholesalers, group purchasing organizations, private insurance companies, etc.). There is some loss of efficiency from all parties involved and there remains the definitive risk that this will continue at least for the remainder of 2021 and possibly 2022. Changing prices involves work for all parties to update their systems, to update their formularies and to communicate changes (e.g. Quebec formulary price decreases are on a fixed schedule and must be communicated by October 29, 2021).

   Complying with all the price changes within 6 months of the start of the new Guidelines

(and maybe less based on when PMPRB confirms target prices) poses a greater risk of errors and of not being able to update all the formularies in Canada in time. Now add the fact that **EVERY** manufacturer would be approaching downstream stakeholders at the same time and you multiply the risks across the board.

The risks to the public payers are worth highlighting, as drug plan managers are experiencing exceptional strain on their systems and the Office of the pan-Canadian Pharmaceutical Alliance is understaffed, contributing to long negotiation timelines. Regulated list price reductions are expected to affect contracts with provincial payers and it is unreasonable to consider that these will all be resolved by the end of the current calendar year.

2. All manufacturers in Canada will have at least one product that will need to establish the appropriate NEAP under paragraph 75. As the PMPRB is aware, there are several products that must apply the DIP methodology to explain average transaction price increases from the changing contracting environment (e.g. loss of contract tenders, new tender award prices). If the PMPRB only communicates the preliminary results of their evaluation for the compliant maximum list price (MLP) in August or September 2021, this would not leave enough time for the manufacturers to argue the case for the appropriate non-excessive average price (NEAP) used in the determination of MLP, **AND** comply with price reductions by December 31st, 2021.

We would also note there are benefits of retaining the two (2) reporting periods, over and above addressing the aforementioned considerations:

1. Provides the time to set up proper technical working groups to deal with emerging procedural questions, because, it is fully expected there will be some granular, detailed and technical matters that are not be captured in the Guidelines, which will need to be clarified for all parties.
2. The current timing of June 30th, 2022 (two reporting periods) does coincide with the current timing of price changes in Canada. Many of the provinces already schedule acceptance of large-scale price changes in the first half of the year. Therefore, changing list prices in this same period in 2022 should work well with the provinces and minimize disruption to their existing processes.

As we understand it, the Guidelines were purposefully written with generic timing (two (2) reporting periods) versus hard coded timing like December 31st, 2021. This would seem to

indicate that the PMPRB wanted to minimize changes in the Guidelines if implementation dates were altered. Therefore, we see no reason to change this reporting period wording with the change of date of implementation from January 1st to July 1st.

We also recognize that the PMPRB makes final calculations in calendar years typically, with only an interim reporting period from January to June of every year. However, given that the compliance requirement in question is a list price reduction, any lack of compliance is simply a mathematical calculation that can be performed as easily mid-year as year-end and should not present any significant challenges for the PMPRB. Furthermore, the year 2022 would be the only exception, as all future years would return to calendar year calculations.

A minimum twelve-month transition period from the date that the Regulations come into force is needed to allow all parties to focus on addressing the COVID-19 pandemic. The previously proposed timeline set out in the January 1st, 2021 Guidelines was both more reasonable and operationally feasible than the current proposal for Merck and our downstream stakeholders.

In fact, complying for December 31st deadline under the January 1, 2021 Guidelines had the issue of coordinating everything during the holiday season, where all stakeholder staffing is reduced. This is not the case with June 30th, 2022.

In looking at the bigger picture, the industry has argued repeatedly that we have not had meaningful consultations throughout this overhaul of the Regulations and Guidelines, especially as the most negatively impacted stakeholder. At every turn, the industry has been subjected to punitive changes. In an earlier draft of the Guidelines (published in June 2020), the PMPRB was willing to effectively provide 3 reporting periods for such compliance. Further shortening the timeline to comply from 2 reporting periods to 1 reporting period is yet another significantly unfavorable change for the industry and goes counter to the federal government's rationale to delay the coming into force of the Regulations by six months until July 1, 2021 in support of the ongoing collective efforts to address the most important challenge facing Canadians today: fighting the COVID-19 pandemic

We are asking the PMPRB to provide some breathing room to allow the industry to properly adjust and adapt to the new requirements. We feel this is a reasonable request in the context

of all the other changes faced by the industry in a very challenging time due to the COVID-19 pandemic.

Merck Canada Inc. (“Merck”) participation in this notice and comment is not intended and should not be interpreted as supporting the amendments to the Patented Medicines Regulations (the “Regulations”) and of the PMPRB Guidelines. Merck continues to have grave concerns about the practicality and legality of the amended Regulations and of the PMPRB Guidelines, which are the subject of ongoing legal challenges.

Sincerely,

Anna Van Acker
President and Managing Director
Merck Canada Inc.