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August 21, 2023

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

Subject: Merck Canada Input on PMPRB's June 2023 Notice and Comment on its Proposed Amendments to the Interim Guidance

On behalf of Merck Canada Inc. (Merck), thank you for the opportunity to provide comments on the Patented Medicine Prices Review Board's (PMPRB's) proposed amendments on the interim guidance, which applies between July 1, 2022 and when a new set of guidelines come into force.

Our submission aims to complement those made by our industry associations, Innovative Medicines Canada and BIOTECanada.

In this submission, we want to make the following recommendations to help finalize the revised interim guidance as well as to guide the PMPRB as it develops its new guidelines to operationalize the revised basket of countries (i.e., the PMPRB11):

1. Engage meaningfully with the sector prior to releasing a draft of the new guidelines
2. Ensure pricing thresholds are aligned with PMPRB's legal mandate
3. Confirm validity of Consumer Price Index increases
4. Provide increased predictability for "Reviewed Medicines"

1. Engage meaningfully with the sector prior to releasing a draft of the new guidelines

In its June 2023 Notice and Comment, the PMPRB indicates its intention to "advance fulsome consultations on the new guidelines".[1] We hope that this signals a willingness on the part of the PMPRB to undertake open, transparent and meaningful consultations on the new guidelines.

In particular, we recommend that the following measures be taken to engage with the pharmaceutical sector to arrive at workable solutions:

- Engage the sector on the proposed new pricing approach prior to releasing a draft of the new guidelines for written stakeholder input, including facilitating an opportunity for IMC's Board of Directors to meet with the PMPRB Board to help foster an open and transparent dialogue.
- Set up working groups, involving pricing experts from this sector, to carefully review how pricing tests would work in practice, looking at a range of case studies to avoid unintended

[1] PMPRB, Notice and Comment - Amendment to the Interim Guidance re: New Medicines, June 20, 2023: https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-new-medicines.html

consequences. This more meaningful consultative approach was customary practice to review proposed guidelines amendments prior to 2016.

The consultations should ultimately aim to develop new guidelines that strike the appropriate balance between ensuring patented medicines are not excessively priced and supporting innovation and our health systems. Specifically, the new pricing framework should be aligned with Canadian governments' efforts to grow the life sciences sector, including the federal government's Biomanufacturing and Life Sciences Strategy and Quebec and Ontario's life sciences strategies. The new guidelines should also strive not to undermine efforts to improve access to medicines, including through recently adopted federal and provincial rare disease strategies.

2. Ensure pricing thresholds are aligned with PMPRB's legal mandate

We are concerned about the reference to the median international price (MIP) threshold in the June 2023 Notice and Comment. This reference point appears to be intended to encourage rights holders to set the list price of medicines below this threshold.

The use of MIP in the proposed revised interim guidance or in any future guidelines as a pricing ceiling is misaligned with the PMPRB's mandate. The courts have clearly stated that the PMPRB's mandate is limited to ensuring drug prices are non-excessive as a function of patent abuse and that once the price of a patented medicine reaches a non-excessive threshold, the PMPRB cannot go further and engage in price control by attempting to push that price even further downwards.[2]

Setting the list price of a medicine at or above the MIP of the PMPRB11 should not automatically be considered "excessive" or an abuse of patent given the changes made to the new basket (i.e., the PMPRB11), which include removing Switzerland and the United States that have less regulated pharmaceutical markets. These changes will already have the effect of constraining the ceiling of list prices and the PMPRB should not attempt to further restrict them by using the MIP as a reference point.

The PMPRB needs to carefully consider the new composition of the basket of countries (i.e., the PMPRB11) when establishing pricing thresholds to ensure they set the bar at the appropriate level (i.e., to ensure non-excessive prices rather than to control prices).

We therefore suggest that the PMPRB refrain from using the MIP as a reference point in the revised interim guidance and in the new guidelines. We recommend that rights holders be considered compliant so long as the list prices are within the range of those found in the new basket of countries.

[2] Merck Canada Inc. et al v. Canada (Attorney General) et al, Quebec Court of Appeal, decision rendered Feb. 18, 2022: https://www.canlii.org/fr/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?resultIndex=1; Alexion Pharmaceuticals v. Canada (Attorney General), 2021 FCA 157: https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do

3. Confirm validity of Consumer Price Index (CPI) increases

The PMPRB's June 2022 Notice and Comment specifies that an increase in the list price of a medicine will not trigger an investigation if it was taken in accordance with the Consumer Price Index (CPI)-based price-adjustment factor during the first filing period of 2022. This statement was restricted to 2022 as new guidelines were anticipated at that time to be in place by 2023.

Changes in the CPI is one of the factors outlined in section 85(1) of the *Patent Act*. The PMPRB must consider each subsection 85(1) factor and cannot ignore any one factor. Patentees must therefore be permitted to take CPI increases during the interim period as well as under the future guidelines.

However, the PMPRB's June 2023 Notice and Comment is notably silent on this issue. To avoid any misunderstanding and remove any uncertainty, we ask that the PMPRB confirm in writing that no review or investigation will be commenced because of a CPI increase taken during the interim period.

4. Provide increased predictability for "Reviewed Medicines"

While we appreciate efforts by the PMPRB in its June 2023 Notice and Comment to provide rights holders of medicines with more predictability, we believe additional steps can be taken to provide market stability. Specifically, we recommend that the PMPRB clarify that it will not reassess or "re-bench" products that are considered "reviewed" provided that the list prices do not increase above the CPI.

In fact, to provide long-term stability and predictability, which is key to creating a competitive and strong pharmaceutical market, we suggest that the PMPRB abandon the notion of re-assessments and re-benching of prices completely for all medicines under the new guidelines.

Again, we thank you for the opportunity to provide comments on the amendments to the interim guidance and look forward to having constructive dialogue with the PMPRB in the context of the upcoming guidelines consultations.

Please do not hesitate to contact me should you have any questions about this submission.

Sincerely,

Jennifer Chan
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Merck Canada Inc.