VIA PMPRB's Consultation 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 Canada's Input on PMPRB's Scoping Paper for the Guidelines Consultations

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) Scoping Paper released in the context of the first phase of consultations to develop new Guidelines to set out how PMPRB staff will review medicine prices and the filing requirements for rights holders.

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

In this submission, we make the following recommendations to help inform the development of new Guidelines that will operationalize the updated *Patented Medicines Regulations*:

1. Adopt pricing thresholds that are within the PMPRB's legal mandate
2. Adopt a complaints-based approach for vaccines
3. Refrain from re-benching medicines over time
4. Grandfather "existing medicines"
5. Allow adjustments of price based on Consumer Price Index (CPI)
6. Avoid measures that are outside the scope of PMPRB's mandate
7. Establish industry working groups to test drive new Guidelines
8. Avoid impeding on innovation and access to vaccines and medicines by adhering to the PMPRB's legal mandate

1. Adopt pricing thresholds that are within the PMPRB's legal mandate

Courts have clearly stated that the PMPRB's mandate is limited to assessing whether drug prices are 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.[1]

It is important to stress that the Quebec Court of Appeal specifically confirmed that the PMPRB's mandate of assessing whether prices are non-excessive is to prevent patent abuse:

[1] *Merck Canada Inc. et al* v. *Canada (Attorney General) et al*, Quebec Court of Appeal, decision rendered Feb. 18, 2022: https://www.canlii.org/en/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?autocompleteStr=2022%20QCCA%20240%20&autocompletePos=1; *Alexion Pharmaceuticals* v. *Canada (Attorney General)*, 2021 FCA 157: https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do

> *That being said, in addition to this regime related to the abuse of patent, a special regime for patented medicines is set out in sections 79 to 103 of the Patent Act. As noted in the overview of the history of the Act, this special regime developed in parallel to the other regime concerning abuse of patent. The reason for this is quite simple. The monopolies granted on medicines by patents raise questions of public interest specific to the pharmaceutical sector, given that the health of Canadians is at issue. A special regime to control abuses resulting from the monopoly granted by a pharmaceutical patent is therefore considered necessary to protect the Canadian public.*[2] ***[emphasis added]***

Therefore, contrary to a statement made by the Board Chair during the December 5th roundtable, thresholds for non-excessive prices are not below the level of abuse of patent. Both concepts must be considered together when the Board assesses the prices of medicines, as they are intrinsically linked.

Further, in determining appropriate pricing thresholds, the PMPRB needs to carefully consider, among other things, the new composition of the basket of countries (i.e., the PMPRB11) to ensure it does not engage in price control. In particular, the new basket of countries was chosen precisely because these countries regulate the price of medicines. Consequently, the price of a medicine in any of these countries is controlled and cannot be considered excessive.

Based on these considerations, Merck suggests a triage measure for investigation that uses the threshold of the highest international price (HIP). Any triaging threshold lower than HIP would be outside of the jurisdiction of the PMPRB and unconstitutional based on court rulings.[3] It would also hinder the introduction of medicines in Canada.

Further, thresholds used by the PMPRB to assess prices should be the same for all medicines, including those that treat rare diseases.

For the small number of medicines that do not have PMPRB11 data shortly after launch, the Board staff can wait three years before assessing a medicine's price. If PMPRB11 data is still unavailable after 3 years, it could consider the other section 85 factors.

2. Adopt a complaints-based approach to vaccines

Most vaccines are subject to an established and well-functioning vaccine recommendation and reimbursement mechanism through the National Advisory Committee on Immunization (NACI) and centralized procurement via the federal government on behalf of the provinces and territories. This process includes competitive tenders and price negotiation and also weighs important considerations related to the procurement of vaccines, such as efficacy, effectiveness,

[2] See paragraph 48 of Merck Canada Inc. et al v. Canada (Attorney General) et al, Quebec Court of Appeal, decision rendered Feb. 18, 2022: https://www.canlii.org/en/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?autocompleteStr=2022%20QCCA%20240%20&autocompletePos=1

[3] *Ibid* at paragraph 49.

safety, security and predictability of supply. In the minority of cases where vaccines are procured individually by Canadians, they are subject to standard market pressures like consumer products because of the high price elasticity of demand. In the very rare instances of potential abuse of market exclusivity, complaints to the PMPRB might be expected.

Given this comprehensive public health procurement system and the very low risk of excessive pricing for vaccines, the PMPRB should only assess the prices of vaccines if a complaint has been filed. Adopting this approach will ensure that the PMPRB does not impede Canadians' access to new and existing vaccines due to additional unnecessary price assessments.

3. Refrain from re-benching medicines over time

The PMPRB should not reassess or re-bench products in cases where the list prices do not increase above the consumer price index (CPI). There should only be an initial price review at launch of medicines or when there is PMPRB11 data, and prices should subsequently be only monitored against the CPI.

A non-excessive price cannot later become excessive simply by the application of a new threshold.

Changes to international prices or fluctuations in exchange rates should therefore not have an impact on Canadian prices. This is because an increase in exchange rate or a decrease of a price in a country of the PMPRB11 for whatever reason cannot result in creating an excessive price in Canada (i.e., a price that is equivalent to an abuse of patent) if the Canadian price did not change. In particular, the fluctuation of prices in other countries are often due to their specific regulatory frameworks, which reflect cost containment measures put in place by those that purchase or reimburse products, similar to the Canadian provinces. The purpose of these regulations is substantially different from the purpose of the PMPRB as regulating patent abuse. Attempts to draw comparisons with international prices over time would therefore be inappropriate for the PMPRB.

In considering the issue of price re-benching, the PMPRB states in its Scoping Paper that "it is important to consider how the Guidelines and its associated price reviews remain relevant at all stages of a medicine's life cycle". This consideration, however, is not relevant to the PMPRB's mandate of monitoring for patent abuse by ensuring prices are non-excessive. Its role is not to bring down prices over time, as this would be akin to imposing price controls.

Further, the PMPRB needs to abandon the notions of re-assessments and re-benching of prices in order to provide long-term stability and predictability for medicines, which are key to creating a competitive and strong pharmaceutical market. This would be aligned with the PMPRB's goal, as stated in the Scoping Paper, to develop new Guidelines that "reduce the uncertainty of the path to market for innovators".

Finally, re-benching prices would not only create uncertainty for innovators, it would also have ripple effects on the entire pharmaceutical ecosystem. This could require continuous renegotiation or adjustments of product listing, distribution and dispensing agreements,

imposing an excessive administrative burden on the whole ecosystem, including provincial governments, insurers, pharmacies and distributors.

4. Grandfather "existing medicines"

Existing medicines (i.e., those with an NOC issued prior to July 1, 2022) that were not deemed to be excessively priced under the previous pricing framework cannot suddenly become excessive because of changes made to that framework. As outlined in the preceding section on re-benching of medicines, once a product has been assessed for excessiveness, there is no further adjustment required unless the manufacturer has increased the price above the CPI. Reducing pricing thresholds for existing medicines based solely on the introduction of a new framework would seem arbitrary and akin to price control.[4]

In addition, changing price thresholds for existing medicines would seriously destabilize the market. Companies developed their business plans and forecasts based on the framework that was in place at the time of authorization and launch of these medicines. Companies cannot successfully carry out their operations in a changing pricing regulatory environment. They need predictability and stability to operate optimally and guide their long-term planning.

Finally, as highlighted in the preceding section, altering price thresholds for medicines would disrupt the entire pharmaceutical ecosystem. In the case of existing medicines, pharmaceutical companies, governments, insurers, pharmacies and distributors would be required to make widespread price alterations simultaneously within a constrained timeline. Implementing price adjustments across the board for all existing medicines concurrently would therefore lead to severe negative repercussions for operations, as well as the procurement and distribution of medicines.

Existing medicines should therefore be grandfathered and only reviewed if the price exceeds the allowable CPI increase.

5. Allow adjustments of price based on Consumer Price Index (CPI)

The PMPRB must consider each subsection 85(1) factor and cannot ignore any one factor in the context of an investigation. [5] Given that the CPI is one of the factors in subsection 85(1) of the *Patent Act*, patentees should always be permitted to take CPI increases, as they always have since the inception of the PMPRB.

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[4] See paragraph 146 of Merck Canada Inc. et al v. Canada (Attorney General) et al, Quebec Court of Appeal, decision rendered Feb. 18, 2022: https://www.canlii.org/en/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?autocompleteStr=2022%20QCCA%20240%20&autocompletePos=1

[5] See, for example, paragraph 120 of Innovative Medicines Canada v Canada (AG), 2020 FC 725, decision rendered June 29, 2020: https://www.canlii.org/en/ca/fct/doc/2020/2020fc725/2020fc725.html?autocompleteStr=2020%20FC%20725%20&autocompletePos=1, and paragraph 47 of Teva Neuroscience GP v Canada (AG), 2009 FC 1155, decision rendered November 12, 2009: https://www.canlii.org/en/ca/fct/doc/2009/2009fc1155/2009fc1155.html?resultIndex=1.

6. Avoid measures that are outside the scope of PMPRB's mandate

Theme 5 of the Scoping Paper asks about efficiencies that could be gained by coordinating decisions and timelines of PMPRB with those of the Canadian Agency for Drugs and Technologies in Health (CADTH), the Institut national d'excellence en santé et services sociaux (INESSS), the pan-Canadian Pharmaceutical Alliance (pCPA) and insurers (public and private).

Integration and coordination measures with these review and reimbursement bodies and insurance plans would be outside of the legislated mandate of the PMPRB, which is restricted to assessing whether drug prices are excessive as a function of patent abuse and not to engage in price control.

As well, we want to stress that the role of the PMPRB is separate and very distinct from the role of these pan-Canadian review and reimbursement agencies and insurance plans. As a review body, the PMPRB price assessment is not a required step in advance of commercialization. CADTH's review and pCPA's negotiations occur independently of PMPRB's assessments and their timelines are not affected by the PMPRB's activities. There are therefore no efficiencies to be gained by implementing coordination measures as part of the PMPRB's framework to align with the processes of these agencies and insurance plans. Measures are needed to accelerate the public/private coverage of new medicines, but these must be introduced by public/private payers at the reimbursement level (i.e., CADTH, pCPA and formulary listings).

Finally, in the December 5th and 6th roundtables, Board members asked several stakeholders about the clinical value of medicines, questioning the evidence levels for approved products and how to address data that may be collected post-drug approval. As well, some stakeholders also raised concerns around the affordability of medicines. We want to stress that the clinical value, the level of evidence and affordability issues fall outside of the legislated mandate of the PMPRB, as they are not relevant for assessing whether the price of a drug is non-excessive. These considerations are relevant for the purposes of Health Canada's regulatory reviews, CADTH and INESSS's health technology assessments, private insurers and pCPA's price negotiations, which assess the therapeutic value of a medicine, the reasonableness of its price in relation to its cost-effectiveness, and the budgetary impact.

In declaring that the pharmacoeconomic factors are invalid, the Quebec Court of Appeal was clear that these considerations are not relevant to assessing abuse of patent but rather, are price control measures.[6] Considering the clinical value of medicines would be similarly irrelevant.

[6] See paragraph 244 of Merck Canada Inc. et al v. Canada (Attorney General) et al, Quebec Court of Appeal, decision rendered Feb. 18, 2022: https://www.canlii.org/en/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?autocompleteStr=2022%20QCCA%20240%20&autocompletePos=1

7. Establish industry working groups to test drive new Guidelines

For Phase 2 of its consultations, the PMPRB needs to set up working groups that involve pricing experts from the sector to carefully review how pricing tests would work in practice, looking at a range of case studies.

This was proposed by several presenters during the December 5th and 6th roundtables. We are hopeful that the PMPRB will implement this suggestion given the openness shown during the roundtables to listen to stakeholders and set a new course for meaningful consultations.

Setting up working groups would also be aligned with the constructive consultative approach that was customary practice to review proposed Guidelines amendments prior to 2016. Previous consultations that included working groups resulted in Guidelines changes that were better understood and accepted by rights holders.

Although working groups require additional time, they would lead to better results and help avoid unintended consequences, which in this context, could cause irreparable harm to patients. Clear and well-understood rules also allow rights holders to comply with the new rules more easily, which leads to a more efficient pricing regime.

One way to ensure that the Guidelines are developed within a reasonable timeframe while still conducting working groups would be to clearly frame the scope of their mandate and specify the issues/problems they need to address to ensure they are productive and efficient.

8. Avoid impeding on innovation and access to vaccines and medicines by adhering to the PMPRB's legal mandate

It is important for the PMPRB to strictly adhere to its legal mandate to avoid unintended consequences on innovation and on access to medicines and vaccines. When the federal government and the PMPRB exceeded this mandate in the past, by attempting to control drug prices, they inadvertently hampered the pharmaceutical ecosystem.

Recent studies show the negative impacts of such overreach on the introduction of new medicines in Canada. For instance, research conducted by IQVIA for Life Sciences Ontario indicates a significant decline in the number of new drugs launched in Canada compared to other developed nations. In 2021, Canada should have experienced double the number of new medicine launches, based on historical trends and global launches.[7]

It is imperative that the PMPRB's new Guidelines do not further contribute to this troubling trend. Medicines play a vital role in keeping Canadians healthy and reducing the burden on healthcare services. This is especially important at a time when health systems continue to struggle to clear pandemic backlogs of care and keep up with increasing demands.

Provinces, which are responsible for the reimbursement of medicines and healthcare delivery and management, are best positioned to strike the appropriate balance between maintaining

[7] IQVIA 2022 study commissioned by Life Sciences Ontario: https://lifesciencesontario.ca/wp-content/uploads/2022/06/ENGLISH.pdf

affordable prices and ensuring access to new medicines, supporting research, and fostering innovation.

By respecting its legal mandate, the PMPRB will allow Canadian governments to pursue their priority efforts in growing the life sciences sector, including the federal government's Biomanufacturing and Life Sciences Strategy (BLSS) and Quebec and Ontario's life sciences strategies. This will also allow Canadian governments to more effectively advance initiatives related to access to medicines, such as rare disease strategies and investments in pharmacare programs.

Again, we thank you for the opportunity to provide comments on the Scoping Paper and look forward to continue to engage with the PMPRB in the development of the new Guidelines.

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

Sincerely,

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Merck Canada Inc.