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Patented Medicine Prices Review Board
Standard Life Centre, Box L40
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Subject: Industry Coalition Submissions *re:* the PMPRB Discussion Guide for Phase 2 Consultations on Guidelines

The industry coalition that brought the constitutional challenge before the Quebec Superior Court and Court of Appeal, composed of Merck, Janssen, Boehringer Ingelheim, Bayer, and Servier (the "**Constitutional Coalition**") is providing written feedback on the PMPRB's discussion guide, titled "Shaping the Future: A Discussion Guide for PMPRB Phase 2 Consultations on New Guidelines" (the "**Discussion Guide**"), published on June 26, 2024. The Discussion Guide is intended to inform this second phase of consultations on the PMPRB's final guidelines which have yet to be adopted ("**Final Guidelines**").

Executive Summary

The Constitutional Coalition provides the present written submissions with the objective of ensuring that the Final Guidelines comply with the constitutional jurisdiction of the PMPRB as defined in the Quebec Court of Appeal's decision in *Merck Canada c Canada*, 2022 QCCA 240 (the "**QCCA Decision**") and the legal principles established therein.

The present submissions will address the elements proposed in the Discussion Guide that directly relate to the QCCA Decision:

(a) The constitutionally appropriate international price comparison (IPC) criteria;
(b) Whether it is constitutionally appropriate to conduct post-initial pricing reviews using criteria other than consumer price index (CPI);
(c) Whether it is constitutionally appropriate to review existing medicines against criteria other than CPI; and
(d) The constitutionally appropriate pricing threshold at the in-depth review stage.

These submissions are in keeping with the Constitutional Coalition's previous submissions of December 2023, submitted in the context of the first phase of consultations.

Legal Context & Background

It is important to reiterate that the QCCA Decision is binding on the PMPRB, and the PMPRB's

mandate and powers are subject to the principles established in the QCCA Decision. The QCCA Decision must therefore inform the drafting, adoption, and application of the Final Guidelines.

The QCCA Decision established that even though non-binding, the Final Guidelines must still be conceived, adopted and applied within the constitutional framework set out in the relevant case law, including notably the QCCA Decision.[1] If the Final Guidelines are not elaborated within these parameters, they are at risk.

In this regard, the QCCA Decision provided important guidance on the scope of the PMPRB's constitutional mandate. The Court confirmed that the PMPRB is not a price regulator. Its mandate is limited to preventing excessive prices flowing from an abuse of the monopoly granted by a patent.[2] The section 85 factors and any resulting Guidelines are to be applied solely in pursuit of this objective.[3] The Court of Appeal noted that any attempt to go beyond this mandate in the pursuit of optimal or reasonable pricing would be an unconstitutional exercise of the federal patent power.[4]

The Final Guidelines must be drafted and implemented in a manner that is consistent with the above principles. If the Final Guidelines run afoul of these principles, for example by establishing arbitrary pricing thresholds or to drive prices below non-excessive thresholds, they are at risk of future court challenges.

Detailed Submissions

a) International Price Comparison

The Constitutional Coalition welcomes the PMPRB's proposal to use IPC as the initial triage measure for the purpose of triggering an in-depth review. However, the Constitutional Coalition continues to urge the PMPRB to adopt the highest international price (HIP) for such pricing threshold and reiterates that any threshold lower than the HIP (i.e. the median international price (MIP) or Midpoint between HIP and MIP) would be a clear unconstitutional exercise of the PMPRB's powers.

HIP is the only IPC threshold that is aligned with the PMPRB's constitutional mandate, as defined in the QCCA Decision and the Federal Court of Appeal's decision in *Alexion*.[5] The QCCA Decision clearly states that an excessive price is one that "exceeds the price for the same medicine in countries reasonably comparable to Canada,"[6] without justification.

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[1] *Merck Canada c Canada*, 2022 QCCA 240 ¶166-167, 175. See also *Alexion v Canada*, 2021 FCA ¶57-63.

[2] *Merck Canada c Canada*, 2022 QCCA 240 ¶143-146, 153, 163, 179.

[3] *Merck Canada c Canada*, 2022 QCCA 240 ¶143-146.

[4] *Merck Canada c Canada*, 2022 QCCA 240 ¶156 (affordability), 204 (consumer products), 228, 235 (price control).

[5] *Merck c Canada*, 2022 QCCA 240 ¶49, 143-146; *Alexion v Canada*, 2021 FCA 157 ¶55-60.

[6] *Merck Canada c Canada*, 2022 QCCA 240 ¶49.

This is for a number of reasons:

Most notably, the PMPRB11 basket is composed entirely of countries considered to be comparable to Canada and that regulate the price of medicines. Indeed, the highest price among a select group of countries with robust regulatory mechanisms for drug pricing provides a ceiling that has been recognized as acceptable – thus non excessive – within similar healthcare economies.

The PMPRB11 countries were selected precisely with the above criteria in mind: their economy, market conditions, and regulatory framework are similar to Canada. According to the Regulatory Impact Analysis Statement which accompanied the change to the basket of countries,[7] the update to the basket of countries was needed "to better align the schedule of countries with the PMPRB's consumer protection mandate and the Government's commitment to improve the affordability of prescription medicines in Canada." The key requirement in the selection of countries was that they "needed to have policy measures in place to constrain free market pricing for medicines. The United States is a primary example of a country that does not satisfy this criterion and was therefore removed from consideration." In addition, countries were chosen that have a similar economic standing to Canada, as measured by GDP per capita, as well as similar market characteristics.

It follows that none of the PMPRB11 prices can plausibly be considered "excessive." The prices in each of these countries have been effectively vetted and considered reasonable by experienced regulatory entities, making the characterization of a price below HIP as "excessive" implausible.

In addition, the examples provided in the Discussion Guide to justify an IPC threshold based on MIP or Midpoint are of no consequence. The PMPRB refers to the Shire BioChem Inc. (Adderall XR, 2008) and Horizon Pharma (Procysbi, 2022) hearings to support potentially lowering the IPC threshold below HIP. However, these are outlier decisions that were rendered under an entirely different regulatory regime based on the PMPRB7, which included the United States and Switzerland, two countries that do not regulate the price of medicines and that are known to have amongst the highest prices for medicines worldwide. These countries were removed from the basket of comparators precisely for these reasons. The Adderall and Procysbi decisions therefore cannot be used by the PMPRB to justify lowering the IPC threshold below HIP, notably given the regulatory change and revised basket of countries.

The MIP and Midpoint thresholds are moreover inappropriate because they may vary over time as a drug is launched in different countries. This would result in an arbitrary variation in the pricing threshold over time. And as stated by the QCCA, arbitrary pricing thresholds are not constitutionally justified.[8]

Finally, the Constitutional Coalition favourably notes that the PMPRB recognizes that "there are instances in which it is possible for a price above the HIP to not be excessive." This is indeed in line with the QCCA Decision, which expressly acknowledges that there may be justification for a

[7] Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements): SOR/2019-298

[8] *Merck Canada c Canada*, 2022 QCCA 240 ¶244.

medicine exceeding the price of other medicines in the same therapeutic class or in countries reasonably comparable to Canada.[9]

b) Post-Initial Price Reviews

The Discussion Guide proposes for the PMPRB to review prices at launch (i.e. initial price review) and subsequently on an annual basis (i.e. post-initial price review, or "re-benching"), wherein drug prices would be compared against not only changes in CPI, but also the same IPC criteria as in the initial review.

The Constitutional Coalition submits that the price of a medicine should be assessed once at launch (or first sale) and then only subsequently monitored against the allowable CPI increase. This is the only assessment frequency and timing that would comply with the clear wording of the QCCA Decision. The QCCA Decision provides that an objective price comparison, consistent with the purpose of the PMPRB, is "to determine an introductory price in Canada that is not excessive and which may subsequently evolve in accordance with the CPI without triggering a more thorough inquiry by the Board."[10] A post-initial price review would therefore conflict with the QCCA Decision.

Furthermore, if the price in Canada does not change but external market conditions do, it is implausible for the Canadian price to be considered excessive in the sense of an abuse of patent. In other words, if there are changes internationally to pricing or fluctuations in the exchange rate, this should not impact an analysis of patent abuse, notably when a price was previously in line with IPC.[11]

As the QCCA notes:

> […] by imposing arbitrary price reductions […] on prices already deemed not to be excessive, the federal government is no longer acting within its jurisdiction over patents of invention and discovery because it does not want to regulate the effects on prices of the monopoly granted by the patent, but rather the market itself.[12]

Re-benching due to changes in market conditions is an attempt to arbitrarily drive prices down beyond acceptable (non-excessive) thresholds and to regulate the market itself.

Furthermore, re-benching would require pharmaceutical companies to renegotiate their product listing agreements with the provinces, since any change in the list price would necessarily impact the confidential pricing agreements negotiated with the provinces. In doing so, the PMPRB would

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[9] *Merck Canada c Canada*, 2022 QCCA 240 ¶ 49.

[10] *Merck Canada c Canada*, 2022 QCCA 240 ¶146 (our emphasis).

[11] See Alexion, par 55-68.

[12] Mer*ck Canada c Canada*, 2022 QCCA 240 ¶ 244.

therefore take on a "role in the optimization of provincial resources and provincial health budgets [and be] directly intruding into provincial heads of power".[13]

Re-benching is an unconstitutional exercise of the PMPRB's mandate. The PMPRB's role in the product's life cycle is limited to monitoring for an excessive price at launch and then subsequently against CPI. If the PMPRB were to engage in re-benching medicines after the initial price review (beyond the allowable CPI increase), this would be akin to price control.

c) ***New versus Existing Medicines***

The Discussion Guide proposes that within a one to three year period following the adoption of the Final Guidelines, the PMPRB will require existing medicines whose price is above HIP to come into compliance with the IPC threshold identified in the Guidelines, failing which an in-depth review may be triggered.

As stated in the Coalition's December 2023 submissions, existing medicines should be "grandfathered," meaning they should not be subject to any additional price review following the adoption of the Final Guidelines (except for allowable CPI increase). In other words, existing medicines sold at prices that were considered non-excessive based on the PMPRB's own evaluation prior to the implementation of the Final Guidelines should continue to be considered non-excessive under the Final Guidelines, with the addition of allowable CPI.

In this respect, the Constitutional Coalition wishes to reiterate that a price cannot become excessive overnight when that price has not changed. Re-assessing the price of existing medicines – already considered non-excessive by the PMPRB's own analysis – will arbitrarily drive existing prices below non-excessive thresholds. This is akin to price control, which the QCCA Decision determined would be an unconstitutional exercise of the PMPRB's excessive pricing mandate.

Not only does grandfathering ensure predictability to patentees over the life cycle of a medicine, but not doing so for existing medicines may require patentees to revise their PLAs with the provinces, as is the case with re-benching (as above).

In sum, the price of an existing medicine, plus the allowable CPI increase, should be considered the maximum non-excessive price for existing medicines, irrespective of new pricing data in the PMPRB11. The PMPRB11 cannot be used to lower the price of existing medicines.

d) In-Depth Reviews

The Constitutional Coalition does not have sufficient information at this stage to judge the constitutionality of the in-depth review process as proposed in the Discussion Guide.

However, the Coalition notes that the PMPRB may not rely on the section 85 factors to drive prices down below otherwise acceptable thresholds. In particular, the therapeutic class comparison (TCC)

[13] *Merck Canada c Canada*, 2022 QCCA 240 ¶ 244.

cannot be used to drive prices down below otherwise non-excessive thresholds; TCC may therefore only be used to justify a price higher than the IPC.[14]

In keeping with the QCCA Decision, the Constitutional Coalition thus urges the PMPRB to adopt a pricing analysis at the in-depth review stage based on a "higher than highest" approach, whereby a price would be considered excessive only if it exceeds the highest price in a given section 85 comparator category (IPC or TCC) – and without justification for such price.

Conclusion

The Final Guidelines must be drafted and implemented in keeping with the QCCA Decision and the legal principles contained therein. If the Final Guidelines depart from the QCCA Decision, they are at high risk of being successfully challenged before the courts. As confirmed by the QCCA Decision, the PMPRB guidelines cannot escape judicial scrutiny on the pretext that they are non-binding: "it would be unacceptable for a regulatory regime to escape constitutional review on the ground that a court could not consider guidelines, whose adoption is prescribed by the Act, and which are indeed determinative in the application of the regime as a whole."[15] The comments in the Discussion Guide such that the Guidelines are only a screening tool to assist the staff are of no assistance in this respect.

The Constitutional Coalition thanks the PMPRB for this opportunity to provide feedback on this second phase of consultations for the Final Guidelines. The Constitutional Coalition is committed to working cooperatively with the PMPRB to implement its constitutional mandate in a manner that is consistent with the QCCA Decision.

Sincerely,

Fasken Martineau DuMoulin LLP

Fasken on behalf of the Constitutional Coalition (Merck, Janssen, Bayer, Boehringer Ingelheim, Servier)

[14] See *Merck Canada c Canada*, 2022 QCCA 240 ¶49, 154, 161-162, 227, 244.

[15] *Merck Canada c Canada*, 2022 QCCA 240 ¶174.