Submission to Patented Medicine Prices Review Board (PMPRB) regarding the 2022 Proposed updates to the PMPRB Guidelines

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Thank you for the opportunity to provide feedback on the draft Guidelines published on October 6, 2022.

We are writing to you on behalf of participating national patient organizations.

Patient organizations, signatory to this submission and previous submissions, have continued to support the protection of Canadians from excessive drug prices and have endorsed the new basket of countries, the PMPRB11. We continue to be strongly supportive of a discrete health technology assessment process for oncology therapeutics, including the deliberative framework developed under the pan-Canadian Oncology Drug Review (pCODR), and adopted by the Canadian Agency for Drugs and Technologies in Health (CADTH). We have also been supportive of the Council of the Federation process under the auspices of the pan-Canadian Pharmaceutical Alliance (pCPA) in the joint negotiation of drug prices for public reimbursement.

Our submission will first set out the context in which the Patented Medicine Prices Review Board (PMPRB) was created and the present context of its mandate and role. We will then present our findings from reviewing the draft Guidelines and the information provided by PMPRB in its webinar on this topic.

We will analyze these in the context PMPRB's role as a quasi-judicial body and draw conclusions about the implications of this role on its duty to conduct its work under the rules of natural justice.

The signatories will draw conclusions and make recommendations as a result.

Patented Medicine Prices Review Board (PMPRB) in the Canadian Context

In brief, the PMPRB was created in 1987 as part of a package of *Patent Act* changes that saw greater patent protection for the brand-name pharmaceutical industry and the removal of mandatory licensing. To ensure that the industry would not take advantage of these gains, by pricing drugs coming into Canada "excessively", the PMPRB was created with a mandate to review proposed drug prices and to determine whether they are "excessive". If prices were found to be excessive based on a comparison with the basket of 7 comparable countries at the time, the prices were required to be reduced and any profits above the approved price must be remitted to PMPRB.

It is important to note that in 1987, PMPRB was the only price review process in Canada nationally. Once a drug was approved for sale in Canada by Health Canada, each province made its own decision about listing a drug on its public formularies and negotiating prices for public reimbursement.

Since then, a pan-Canadian process for health technology assessment was created for all provinces but Quebec (which has its own process known as INESSS[1]), now known as the Canadian Agency for Drugs and Technologies in Health (CADTH). CADTH was the creation of F/P/T and it makes recommendations to public payers for reimbursement, with or without conditions.

Furthermore, the Council of the Federation has created a pan-Canadian pharmaceutical negotiation process, whereby participating provinces/territories negotiate collectively. This process is known as the pan-Canadian Pharmaceutical Alliance (pCPA), and its negotiations are confidential. Provinces and territories participating in negotiations still have an opportunity to review the price at the provincial level after negotiations, and may or may not, decide to reimburse the drug, or may decide to set their

[1] Institut national d'excellence en santé et en services sociaux

own conditions for reimbursement. The pCPA member jurisdictions have been expanded to include federal drug benefit programs as well, including Non-Insured Health Benefits (NHIB), Correctional Services of Canada (CSC) and Veterans Affairs Canada (VAC).

With these additional checks and balances on Canadian drug prices, the role of the PMPRB must continue to remain within its mandate, which is relatively narrow.

Role of the PMPRB

The Law

As described above, the PMPRB is created, and derives its mandate, from the federal *Patent Act* and *Regulations*. The *Regulations* provide a basket of 11 countries for comparison to determine whether the price a manufacturer wants to charge in Canada is "excessive".

Relevant Court Interpretations of its role

Court cases have interpreted this mandate. In February 2022, the Quebec Court of Appeal in *Merck Canada inc. et al. v. Canada* stated in effect that the constitutional role of the PMPRB is limited to prevent "excessive" prices derived from the monopoly conferred by a patent. Its role is limited to "excessive" pricing and patent abuse and does not include price control and the regulation of an industry.[2]

The Court also found that reference pricing is a legitimate way to assess excessive pricing. Moreover, the list of comparison countries is not static and can evolve. The Court of Appeal found that the fact that such a substitution of reasonably comparable countries could have the effect of reducing drug prices in Canada is irrelevant to the analysis of the constitutional validity of the measure, since the objective pursued remains that of ensuring price competitiveness in Canada relative to those abroad.[3]

The Court also made statements about how the PMPRB's mandate had to be narrowed and does not extend to pure price control:

> [243] In summary, federal regulation of the price of patented medicines is constitutional to the extent that it has as its pith and substance to prevent the negative effects on prices of the monopoly granted by a patent. Conversely, federal regulation is unconstitutional to the extent that it no longer seeks to control the [negative] effect of the patent monopoly on prices (our translation).

Similarly, the Court generally expressed agreement with recent precedents that the control of excessive prices must result from the monopoly conferred by a patent.[3]

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[2] Merck Canada inc. c. Procureur général du Canada, 2022 QCCA 240 (CanLII), <https://canlii.ca/t/jmjbm>, consulté le 2022-11-20

[3] Quebec Court of Appeal Renders Major Decision on the PMPRB. https://www.fasken.com/en/knowledge/2022/02/decision-on-the-pmprb

Legal Obligations as a Quasi-Judicial Body

It is well recognized that the PMPRB is a quasi-judicial agency of the federal government created under *the Patent Act*.[4] It reports in through Health Canada for purposes of the drug pricing Regulations while other parts of the *Act* report in through the Minister of Innovation, Science and Economic Development. As described above, it is responsible to determine whether the price being proposed for the sale of a drug or other treatment in Canada is excessive. If the price is deemed to be excessive based on the criteria set out in the Regulations to the *Patent Act*, the manufacturer must lower the price to meet these criteria or will not be permitted to sell the product in Canada.

Quasi-judicial bodies including Agencies, Boards, and Tribunals, make decisions on behalf of the government, when it is impractical or inappropriate for the government to do so itself. They must behave impartially in their decision-making process.[5]

Quasi-judicial bodies are under a duty to act in accordance with the rules of natural justice, giving persons specially affected by the decision a reasonable opportunity of presenting their case, listening fairly to both sides and reaching a decision untainted by bias.[6] They also has the right to engage specific expertise to assist in providing needed advice and input.[5]

The rules of natural justice apply to all decision makers and those advising them, *e.g.,* the Board of Directors, the staff of PMPRB and any advisors on whom they rely.

Since these bodies are created to move tasks, in whole or in part, out of the traditional parliamentary and Cabinet processes, the agency itself should opt for public involvement in the decision-making process.[7]

[4] Patented Medicine Prices Review Board (PMPRB). 2022 Proposed updates to the PMPRB Guidelines. https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines-2022/Draft-Guidelines-2022.pdf

[5] Blake S. *Administrative Law in Canada*. 6th ed. Markham, Ont: LexisNexis Canada; 2017.

[6] Yogis JA, Cotter C, Gifis SH, Barron's Educational Series I. *Barron's Canadian Law Dictionary*. 6th ed. Hauppauge, N.Y. : Barron's Educational Series; 2009.

[7] Mullan DJ. Administrative Tribunals: Their Evolution in Canada from 1945 to 1984. In: Bernier I, Lajoie A, eds. *Regulations, Crown Corporations and Adminstrative Tribunals: Royal Commission*. Toronto: University of Toronto Press; 2016:155-201. doi:10.3138/9781442656888-007

Relevant Court Interpretations of its process

One of the obligations of the PMPRB is to include as part of its process a reasoned explanation for its decisions. In this regard, we would refer to the *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)* regarding a decision by PMPRB. In para 25, the Court concluded "a reviewing court must ultimately be satisfied that the [administrator's] reasoning 'adds up'."[8]

The Court indicated that the requirement in some cases of a reasoned explanation is higher than in others:

> "In some cases, however, the requirement of a reasoned explanation is higher:
>
> Where the impact of a decision on an individual's rights and interests is severe, the reasons provided to that individual must reflect the stakes. The principle of responsive justification means that if a decision has particularly harsh consequences for the affected individual, the decision maker must explain why its decision best reflects the legislature's intention."

The court in *Alexion* relied on an earlier court case, *Vavilov,* which in effect, required two related components for a reasoned explanation by PMPRB, *i.e.* adequacy as well as logic, coherence and rationality.

By "adequacy", the court described a reviewing court's ability to trace and understand an "internally coherent and rational chain of analysis". By failing to reveal a rational chain of analysis, or where it is "[im]possible to understand the decision maker's reasoning on a critical point", the duty of "adequacy" in the explanation is not met.

In relation to "logic, coherence and rationality", the decision maker falls short when it "fail[s] to reveal a rational chain of analysis", the analysis is unreasonable, irrational or logically flawed.

[8] Alexion Pharmaceuticals Inc v Canada (Attorney General), [2021] FCJ No 812, 2021 FCA 157

Findings from Draft Guideline Review

We find that the basic rules of natural justice, discussed above, have not been met in the 2022 draft Guidelines:

1. The PMPRB has not set out any Principles or Objectives for its guidelines, nor the parameters of its jurisdiction or the criteria by which this jurisdiction is going to be applied. Thus, relevant stakeholders, including applicants, are not provided clear criteria by which applications are being judged; are not necessarily entitled to all information the PMPRB is gathering nor is there a commitment to a transparent full decision with reasons for the decision.

2. There is not enough information provided in the 2022 draft Guidelines to permit a potential applicant to analyze its application in the context of the draft Guidelines, or even to determine what ought to be included in that application for it to be complete. One piece of missing information is whether historical approaches to determining Domestic Therapeutic Class Comparison (dTCC) will be applied to new medicines going forward.

3. The staff of the PMPRB is charged with conducting investigations based on a complaint, with or without evidence; when the list price exceeds the CPI or when there are no available prices for the PMPRB11 basket of countries. The draft Guidelines do not, however, provide any "guardrails" to ensure impartiality and avoid bias. The staff appears to have unfettered power to determine the investigation process, none of which is made public.

4. The draft Guidelines provide no explanation of how a decision will be communicated and whether the reasons for a decision will be made available.

There may well continue to be profound uncertainty for industry decision makers moving forward.

While patients want reasonable pricing and access regimes for medicines in Canada, we want to ensure no unreasonable and unnecessary barriers to treatment access are created.

Conclusion and Recommendations

In conclusion, we have been unable to determine what criteria in 2022 draft Guidelines will be used, and how they will be used, in reviewing applications. This lack of transparency leaves all stakeholders mired in uncertainty.

Without clear and transparent processes including tools, metrics, algorithms, and rules, stakeholders are being asked to apply to PMPRB without prior knowledge of the process involved in the review, the criteria by which submissions are evaluated, and any other relevant information for the applicant.

In our view, this lack of transparency is contrary to the rules of natural justice by which the PMPRB is bound as a quasi-judicial body.

Below are our recommendations to the PMPRB:

Recommendation 1: PMPRB should postpone implementation of the 2022 draft Guidelines until it has conducted a complete legal analysis of its requirements as a quasi-judicial body in order to meet the rules of natural justice. These should be included in the revised 2022 draft Guidelines.

Additionally, in these circumstances, the stakes for the applicant, and for access to treatments by patients, are very high. The Guidelines should, therefore, ensure, among other things, that decisions will be made public with reasons that include the decision maker's explanation of why its decision best reflects the legislature's intention.

Recommendation 2: Revised PMPRB draft Guidelines must undergo final stakeholder consultation prior to coming into effect and ensure that the final Guidelines align in their purpose and content with other public health policy systems. This final stakeholder consultation must be allowed adequate time for meaningful stakeholder consultation.