Patented Medicine Prices Review Board publishes new guidelines for PMPRB staff: Finally, some guidance for patentees

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On June 30, the Patented Medicine Prices Review Board (PMPRB) published new Guidelines for PMPRB Staff (the Guidelines) that will take effect on Jan. 1, 2026. These new Guidelines are described as non-binding, and were developed to address both amendments to the *Patented Medicines Regulations* and new case law.

In June 2019, amendments to the *Patented Medicines Regulations* were announced; BLG published a previous Insight summarizing them. These amendments were challenged in both the Federal Court and the Québec Superior Court. Both courts struck down parts of the amendments as being *ultra vires* the *Patent Act*, or unconstitutional.

These decisions were upheld by the Federal Court of Appeal and the Québec Court of Appeal (with the QCA finding additional parts of the *Regulations* to be unconstitutional). No appeal to the Supreme Court of Canada was taken. Thus, the appeal court decisions invalidating key parts of the *Patented Medicines Regulations* governed, and those parts of the *Regulations* could not be implemented by the PMPRB.

The government then published new amendments to the *Patented Medicines Regulations*, repealing those sections found to be unconstitutional and *ultra vires*. These new Guidelines have been long anticipated.

Role of the Guidelines

The Guidelines describe themselves as non-binding, but "designed to ensure procedural fairness and consistency in that all similarly placed Rights Holders are subject to the same process and process timelines." (para 4) They are directed to PMPRB staff and describe a two-step screening process. The goal of this new process is to prioritize the cases that are recommended for a hearing and to allow the PMPRB to focus its hearing-related resources efficiently. The Guidelines state that they are designed to provide transparency into this process. The Guidelines are not intended to be a pricing framework, nor to provide certainty on outcomes, nor to suggest or set prices in Canada.

As these new guidelines are directed to Board Staff, and not patentees, they no longer contain the policies and procedures found in the 2017 Guidelines. Patentees are directed to the *Patented Medicines Regulations* for reporting requirements.

The Guidelines give an overview of the PMRPB's mandate as defined in the *Patent Act*, and confirm that the *Patent Act* does not define what an excessive price is, but rather sets out factors that must be taken into consideration.

A closer look at the Guidelines

Jurisdiction

The PMPRB continues to have jurisdiction over a patentee and any person entitled to exercise rights in relation to the patent.

Patent Act amendments have resulted in a definition of medicine. The term "medicine" (s. 79(1)) includes a drug as defined in s. 104:

> ***drug*** means a substance or a mixture of substances manufactured, sold or represented for use in
>
> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; or
>
> (b) restoring, correcting or modifying organic functions in human beings or animals. (drogue)

The Guidelines reiterate the PMPRB's historical interpretation that these definitions "exclude medical devices per se (as opposed to active substances used in medical devices), in vitro diagnostic products and disinfectants that are not used in vivo."

Patents must be reported to the PMPRB if they "pertain to a medicine". (s. 79(2)). The phrase "pertains to" continues to be interpreted broadly. As was the case previously, if the patented invention is intended or capable of being used for a medicine, or the preparation or production of a medicine, it must be reported.

However, the Guidelines have been amended to reflect recent caselaw that there must be a "rational connection or nexus between the invention described in the patent and the medicine" (Para 30). This addition is cited as meaning to capture the second FCA decision in *Galderma* (also summarized here), which set aside the PMRPB's order that a patent with claims to the use of 0.3 per cent concentration of the active ingredient was reportable with respect to a product containing only a 1 per cent concentration, as the patent did not pertain to the medicine.

Review process

The new two-step screening process in the PMPRB Guidelines is designed to prioritize cases for potential excessive pricing hearings. Neither step determines whether a price is excessive: they only determine which cases are recommended to the chairperson for a hearing. The discretion to issue a Notice of Hearing rests with the chairperson, and

the determination of whether a price is excessive is made by a hearing panel during a public hearing.

Initial Review (first step)

- The Initial Review is conducted using the first semi-annual price filing of a patented medicine. It compares the list price(s) in Canada with the highest international price (HIP) among the eleven Schedule Countries. If the list price exceeds the HIP, the medicine is subject to an In-Depth Review.
- If an IPC cannot be conducted due to the absence of list prices in the Schedule Countries, the list price is considered reviewed for the Initial Review and is not reviewed again until the Annual Review.
- The service standard for the Initial Review is to advise Rights Holders within 60 days of the filing deadline, whether their medicine is subject to an In-Depth Review.

Annual Review (first step)

- The Annual Review applies the same International Price Comparison (IPC) HIP criteria and methodology used during the Initial Review. However, it focuses on the most recently filed pricing data — both domestic and international.
- Staff will also compare the price change of each patented medicine against changes in the Consumer Price Index (CPI).
- If an IPC cannot be conducted due to the absence of list prices in the Schedule Countries, an In-Depth Review can be initiated based on change in the CPI.
- An In-Depth Review will be initiated if changes are above the CPI, unless no price increase was taken in the previous year, and the increase is lower than or equal to the total CPI change over two years.
- The service standard for the Annual Review is to advise Rights Holders within 60 days of the filing deadline, whether their medicine is subject to an In-Depth Review.

In-Depth Review (second step)

- The In-Depth Review involves a comprehensive analysis of all information related to the section 85 factors to prepare a recommendation to the chairperson on whether a hearing should be held.
- When an In-Depth Review is started, a staff scientific team will identify comparators for a Therapeutic Class Comparison (TCC), to address one of the factors in s. 85(1)(b) of the Patent Act. Rights holders will be given an opportunity to provide input on the TCC assessment.
- If one DIN meets the criteria for In-Depth Review, all associated DINs sold by the rights-holder will be considered as part of the In-Depth Review.
- The In-Depth Review considers all available prices in the Schedule Countries and does not presuppose that prices above or below the HIP are excessive or not. The determination of excessiveness is made by hearing panels.
- The In-Depth Review could take between 12 and 28 months to complete, depending on its complexity.
- If an In-Depth Review has been closed, that patented medicine will not be subject to another In-Depth Review for at least the two subsequent filing periods.

- If there is a complaint, the Board Staff will proceed directly to the In-Depth Review step.

Transition period

New medicines will be subject to the Initial Review process as soon as these Guidelines come into effect, namely Jan. 1, 2026. Existing medicines will be subject to transitional measures. The first Annual Review for existing medicines will occur two years after the Guidelines come into effect. At this point, Board Staff will only apply the IPC criterion. The application of the Consumer Price Index criterion will begin during the next Annual Review.

Undertakings and settlement proposals

An undertaking can be submitted at any point during the In-Depth Review, and up to two months after being advised that Board Staff recommend a hearing to the chairperson. Staff and the chairperson will not provide guidance on the substance of any proposed undertaking. Undertakings that are accepted are intended to resolve an In-Depth Review. They do not provide price assurances going forward. (para 104)

Once a Notice of Hearing has issued, an undertaking is no longer available. Formal settlement must be agreed upon by the hearing panel.

Other information

The Guidelines also include more details about the steps described above, as well as hearings and orders that the Board can make. An appendix contains detailed non-limiting lists of information that the Board Staff can consider when assessing the factors set out in s. 85(1) as well as other considerations. It also provides some commentary as to scenarios that may tilt decisions one way or the other. In addition, some case studies are provided.

Conclusion

The revised PMPRB Guidelines attempt to emphasize procedural fairness and transparency in the review process. They set out a structured approach to the Board Staff for reviewing and prioritizing cases. While the Guidelines do not set price ceilings, they require patentees to be vigilant about compliance with the factors that could trigger In-Depth Reviews. For further details or specific inquiries, please reach out to the key contacts below.

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