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Patented Drug Pricing: The PMPRB Releases New Price-Review Guidelines

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On June 30, 2025, the Patented Medicine Prices Review Board (the PMPRB) published its new Guidelines for PMPRB Staff (Guidelines).[1] The Guidelines outline the new two-step process by which PMPRB staff will monitor, review, and make recommendations on patented drug prices.

The Guidelines come as a result of proposed amendments to the *Patented Medicines Regulations*[2] in 2019, multiple court proceedings to challenge the proposed amendments, and a number of consultations with stakeholders.[3]

These new Guidelines will come into effect on January 1, 2026.[4]

Background

The PMPRB is an independent, quasi-judicial body in Canada that monitors the prices of patented medicines sold in Canada to ensure they are not excessive.[5]

The Guidelines will change oversight of drug pricing. Pharmaceutical companies — especially those marketing patented medicines — should understand the new Guidelines and understand their impact when setting or adjusting patented drug prices in Canada.

Under the new Guidelines, companies are permitted to set their own list prices for patented medicines and are not subject to pre-set pricing by the PMPRB.[6] The PMPRB can review the listed prices at any time and, after a hearing is conducted, they can decide whether the price is excessive.[7]

The New Two-Step Review Process

The PMPRB will now utilize a two-step screening process to prioritize cases that should be recommended for a hearing.[8]

Step One

The process will start with an Initial Review, where the PMPRB staff will compare the Canadian list price of a patented medicine to the highest price reported out the following 11 countries: Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, and the United Kingdom (collectively, the PMPRB11).[9]

If the Canadian price is higher, then the drug will move to the In-Depth Review stage.[10] An Annual Review will also be conducted every January on each patented medicine under the PMPRB's jurisdiction to compare the patented medicine's price against the list prices in the PMPRB11.[11] The PMPRB will use the Annual Review to determine whether the patented medicine will be subject to an In-Depth Review.[12]

Step Two

In the In-Depth Review stage, the PMPRB will consider the information related to the section 85 factors of the *Patent Act*[13] discussed below to prepare a recommendation on whether the drug pricing matter should be brought to a hearing.[14] Factors to be considered may include, but are not limited to:

- the price at which the patented medicine has been sold in the relevant market;
- the price at which other medicines in the same therapeutic class have been sold in the relevant market;
- the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada; and
- how any price change for the patented medicine compares to changes in the Consumer Price Index.[15]

If a hearing is ordered, then a panel of at least two PMPRB members will be selected to sit on a hearing panel. Hearings are public and are "de novo" proceedings, meaning they start fresh and assess the evidence from a blank slate.[16]

If the hearing panel determines the list price was excessive, it can order the company to lower the price going forward in the market and to offset the amount of excess revenue earned.[17] In serious cases where a company has been deliberately selling at an excessive price for an extended duration, it can order a repayment of up to twice the amount of excess revenue.[18]

If a company wishes to avoid a hearing, the company may submit an Undertaking to the PMPRB, which is a unilateral promise to take certain steps. Undertakings are not binding agreements. If the PMPRB accepts the Undertaking, then the In-Depth Review is closed.[19]

However, if a Notice of Hearing is issued, then an Undertaking is no longer an available option. In this scenario, the company may only seek to settle the matter through a formal settlement approved by the hearing panel or continue with the full hearing process.[20]

Beware of Complaints

Under the new Guidelines, the PMPRB will automatically begin an In-Depth Review if a complaint is filed against a company by the federal Minister of Health, a provincial or territorial health minister, or a senior official from a publicly funded drug program. Complaints from other companies will not lead to In-Depth Reviews.[21]

If the medicine is patented and sold in Canada, and the complaint comes from one of the listed parties, then the PMPRB must investigate the complaint.[22]

Takeaway

Going forward, companies should continue to carefully craft their pricing strategies for patented medicines in Canada in light of the PMPRB's new Guidelines. The Cassels Regulatory and Intellectual Property Groups would be pleased to discuss how these Guidelines may impact your business.

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[1] Government of Canada, News Release, "PMPRB releases new Guidelines to monitor and review drug prices" (June 30, 2025) [PMPRB News Release].

[2] *Patented Medicines Regulations*, SOR/94-688.

[3] Government of Canada, "Guidelines for PMPRB Staff" (2025) at paras 2, 3 [Guidelines].

[4] PMPRB News Release, s*upra* note 1.

[5] Guidelines, *supra* note 3 at para 1.

[6] *Ibid* at paras 5, 6.

[7] *Ibid* at para 6.

[8] *Ibid* at para 44.

[9] *Ibid* at para 44.

[10] *Ibid* at para 50.

[11] *Ibid* at para 53.

[12] *Ibid*.

[13] *Patent Act*, RSC 1985, c P-4, s 85.

[14] Guidelines, *supra* note 3 at para 74.

[15] *Ibid*.

[16] *Ibid* at para 109.

[17] *Ibid* at para 112.

[18] *Ibid* at para 113.

[19] *Ibid* at paras 102, 104.

[20] *Ibid* at para 106.

[21] *Ibid* at paras 66, 68, 70.

[22] *Ibid* at para 66.