

An Opportunity to Reshape Patented Medicines Regulation in Canada

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July 1, 2016

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1. The PMPRB

Patent Act

Patented Medicines Regulations

Patent Act

Compendium of Policies, Guidelines and Procedures

2. Nature of the Reform

1. Conducting initial screenings on drugs based on potential for abuse of statutory monopoly rather than therapeutic benefit;²
2. Revisiting the manner in which international price comparisons are made, either by changing the composition of the PMPRB7 Countries or changing how price ceilings are set relative to the PMPRB7 Countries;³
3. Changing the way that drugs in the “slight or no improvement” category are priced;⁴
4. Re-evaluating the role of the CPI in determining whether a drug is excessively priced;⁵ and
5. Considering whether the price of a drug “in any market” should be given greater weight in determining whether a drug is priced excessively.⁶

3. Stakeholder Feedback

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- What the word “excessive” means in relation to drug pricing;
- The amount of weight to be placed on international public list prices when determining price ceilings for drugs;

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- The relative weighting that should be given to the Section 85 Factors;
- The perceived relationship between research and development conducted in Canada and excessive price ceilings; and
- Any other aspects of the Guidelines that may warrant reform.⁸

4. The Next Steps

October 24, 2016

Phase	Steps	Proposed Timelines
Phase 1: Consult with Stakeholders on Issues	Publish Discussion Paper (June 24, 2016) Meet with various stakeholder groups across Canada Obtain written comments from stakeholders and the public on questions in the discussion paper (Deadline October 24, 2016) Gather and analyze all results from Phase 1 of consultation	Summer/Fall 2016
Phase 2: Engage Stakeholders and Gather Expert Input	Public Policy Hearing – invite stakeholders to appear before the Board and make representations in support of their written submissions	Fall 2016/Winter 2017
Phase 3: Presentation of Proposed Changes	Publication of proposed changes to Guidelines for comment through Notice and Comment Process Strike multi-stakeholder forum(s) on specific issues and proposed changes to the Guidelines	Spring/Summer 2017

October 24, 2016

¹

Patented Medicine Prices Review Board, "PMPRB Guidelines Modernization Discussion Paper" (June 2016),
online

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²

Ibid at pg 14.

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Ibid at pg 17.

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Ibid at pg 17.

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Ibid at pg 19.

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Ibid at pg 19.

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Patented Medicine Prices Review Board, "Strategic Plan 2015-2018" (December 2015),
online

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Discussion Paper, *supra*, at pg 22.

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