The PMPRB: Where It Started and Where It Is Going

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Thirty years ago, in 1987, the Patented Medicine Prices Review Board (PMPRB) was formed as an independent quasi-judicial agency as part of amendments in the *Patent Act*. The creation of the PMPRB was to protect Canadian consumers by ensuring that manufacturers did not charge excessive prices for patented medicines. The industry agreed to the introduction of price controls and the members of the Pharmaceutical Manufacturing Association of Canada (PMAC) now Innovative Medicines Canada (IMC) committed to double their R&D spending to 10% of sales by 1996. The PMPRB mandate remains to ensure prices are not excessive and price increases do not exceed the Consumer Price Index.

The *Patent Act* identifies factors for the board to consider when determining whether the price of a patented medicine is excessive. The regulations establish the requirements of regulatory activities which are then operationalized through the PMPRB's guidelines. The guidelines were developed in consultation with various stakeholders including consumer groups, provincial ministries of health and the pharmaceutical industry.

Since conception, the PMPRB has revised the guidelines through consultation with the above mentioned stakeholders to understand the impact of proposed changes. There have been few revisions and they were based on adaptation of managing the PMPRB requirements. The regulations have been amended accordingly to align with the guidelines.

In 2015, the PMPRB released its strategic plan for 2015-2018 with four strategic objectives. Consumer-focused regulation and reporting as well as framework modernization are two of the strategic objectives that led to the release of the discussion paper: Guideline Modernization in 2016. The dis-

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cussion paper asked pointed questions for feedback from the public and stakeholders, garnering 66 responses.

Following the publication of the responses, in January 2017 Health Minister Jane Philpott, stated in an exclusive interview with the Fifth Estate that she plans to change Canadian regulations to force patented drug companies to lower their prices, thus supporting the PMPRB's objectives.

In May 2017, Health Minister Jane Philpott announced and released through Health Canada a regulatory proposal titled, "Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations." Consultations on the regulatory changes related to the PMPRB and the ways in which patented medicines will be reviewed are open to feedback from provinces and territories, consumer groups, private payers, the pharmaceutical industry, other stakeholders, and any interested members of the public, prior to their pre-publication in Part I of the Canada Gazette in the Fall 2017. Further consultations on the PMPRB compendium of policies, guidelines and procedures will follow from the regulatory amendments.

The five important proposed changes to the regulations include:

1) Introducing new factors to help determine whether a price is excessive. Factors that would be considered:

- The pharmacoeconomic evaluation of the medicine;
- The size of the market for the medicine in Canada and in countries other than Canada; and
- Gross domestic product in Canada.

2) Amending the list of countries used for international price comparisons:

- Proposed countries include: Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, South Korea, Spain, Sweden, United Kingdom (removal of Switzerland and the United States).

3) Reducing regulatory burden for generic drugs with a patent.

4) Modernizing reporting requirements for patentees.

5) Providing information related to third party rebates

- To require patentees to report to the PMPRB all indirect price reductions, given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit in Canada.

So, what does all this mean? The regulations and guidelines are about to undergo significant changes and manufacturers will need to incorporate these changes going forward in their Canadian strategic planning timelines, budgets, and resource allocation. One thing is for certain, the PMPRB will not be what it was and that means adaption by patentees with more considerations when evaluating the Canadian market.

For more details, the report, "Protecting Canadians from Excessive Drug Prices - Consulting on Proposed Amendments to the Patented Medicines Regulations," is available at www.canada.ca/en/health-canada/programs/consultation-regulations-patented-medicine/document.html#a3.

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Questions?
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