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Pharma in brief – Canada

PMPRB initiates consultations on changes to guidelines for determining excessive pricing of patented medicines

Summary

On June 24th, the Patented Medicine Prices Review Board (**PMPRB**) published *"PMPRB Guidelines Modernization Discussion Paper"* (**Discussion Paper**). The Discussion Paper is part of the PMPRB's Strategic Plan for 2015 - 2018 in order to obtain feedback from stakeholders on possible changes to its Compendium of Policies and Procedures (**Guidelines**) on how the excessive pricing factors under section 85 of the *Patent Act* are applied (**Excessive Price Factors**).

Background on Guidelines Modernization

The PMPRB monitors prices of patented medicines sold in Canada to ensure they are not excessive and reports on pharmaceutical trends and the research and development spending of patentees. The PMPRB states in the Discussion Paper that is has initiated consultations to reform and modernize its Guidelines based on its observations that Canadian patented drug prices have been steadily rising relative to prices in the seven comparator countries (**PMPRB7**), while investments in R&D have declined.[1]

According to the PMPRB, Guidelines modernization is necessary to bring the PMPRB in line with today's pharmaceutical practices and international best practices.[2] In particular, the PMPRB observes the following changes to its regulatory environment that necessitate reform: (i) price and IP are no longer particularly effective policy levers for attracting pharmaceutical R&D; (ii) confidential price discounts frustrate international efforts to contain pharmaceutical spending based on public list prices; (iii) a growing price gap between different payers based on relative negotiating power; and (iv) increasing availability of high-cost speciality medicines.[3]

Excessive Price Factors – Key Areas Identified for Reform

The PMPRB notes that although the Guidelines have been revised as recently as 2010, there have been no significant changes to how the PMPRB applies the Excessive Price Factors since 1993. In the Discussion Paper, the PMPRB highlights aspects in particular need of reform, including:

- The categorization of new patented drugs based on therapeutic benefit: the PMPRB proposes moving away from linking price to therapeutic benefit, in favour of screening based on indicators of potential abuse of statutory monopoly.[4]

- International price comparisons: the PMPRB proposes that the PMPRB7 composition should change to better align with R&D in Canada, and/or the manner in setting price ceilings based on PMPRB7 should be revised downward to align with more restrictive approaches taken in other countries.[5]

- Domestic price comparisons: the PMPRB proposes that new patented drugs in the "slight or no improvement" category should no longer be permitted to price at the top of the domestic therapeutic class, and lower price ceilings could act as a proxy for "true" drug prices net of rebates and discounts.[6]

- Price increases based on changes in the Consumer Price Index (**CPI**): the PMPRB discusses a more stringent approach taken by other countries that either refuse price increases or require decreases at specific intervals on the basis that the marginal cost of producing a drug should decrease over time with competition. The PMPRB proposes that the CPI be considered differently than under the current Guidelines to determine whether a price decrease may be appropriate.[7]

- Any market price review: the Discussion Paper states "in any market" (e.g., wholesaler, pharmacy, hospital, provincial) excessive price review presently only occurs at introduction or when a medicine is under investigation. Extending the scope of price assessment "in any market" could overcome the perceived lack of price transparency between different payers, and play a more prominent role in determining if pricing is excessive.[8]

Consultation Questions on Excessive Pricing Factors

At this stage, the PMPRB is seeking general feedback in the form of responses to a list of 12 broadly formulated questions on the Excessive Price Factors (*see page 22 of the Discussion Paper*). These broad questions include, for example:

- "Given that it is standard industry practice worldwide to insist that public prices not reflect discounts and rebates, should the PMPRB generally place less weight on international public list prices when determining the non-excessive price ceiling for a drug?"

- "Should the PMPRB set its excessive price ceilings at the low, medium or high end of the PMPRB7 countries?"

- "Should price discrimination between provinces/territories and payer types be considered a form of excessive pricing and, if so, in what circumstances?"

The PMPRB is also looking to receive feedback on other aspects of the Guidelines that are not specifically mentioned in the Discussion Paper that may warrant reform.

Consultation Period

Written comments and feedback may be submitted to the PMPRB by **October 24, 2016**. All comments are public and will be published on the PMPRB website. Following the consultation period, the PMPRB aims to present the proposed changes to the Guidelines in the spring/summer of 2017.

Link to Discussion Paper:

PMPRB Guidelines Modernization Discussion Paper

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Footnotes

1. PMPRB Guidelines Modernization Discussion Paper, June 2016, p. 6 (“Discussion Paper”).
2. Discussion Paper p. 10.
3. Discussion Paper p. 12.
4. Discussion Paper pp. 14-15.
5. Discussion Paper, p. 17.
6. *Ibid*.
7. Discussion Paper, p. 19.
8. *Ibid*.

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