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Re: Patented Medicine Prices Review Board (PMPRB) Draft Guidelines for PMPRB Staff. Administrative Process for Excessive Price Hearing Recommendation

Submitted via webportal

The December 2024 "Draft Guidelines for PMPRB Staff" state that "*The PMPRB is an independent quasi-judicial statutory body with a mandate to monitor the prices of patented medicines sold in Canada to ensure that they are not excessive.*" The scope of this mandate was clarified in the judicial guidance from the *Merck Canada Inc*. c. *Procureur general du Canada* and *Innovative Medicines Canada* v. *Canada* (*Attorney General*) challenges. Both Courts confirmed that the PMPRB is not a price regulator, rather its mandate is limited to preventing excessive prices resulting from an abuse of the monopoly granted by a patent.

These draft guidelines place significant emphasis on the factors included in subsection 85(1) of the Patent Act and while the Act is prescriptive with respect to the Board's requirement to consider these factors when reviewing the prices of medicines, it is mute with respect to when or how often those factors are considered. For greater clarity, while the Act specifies which factors may be considered, there is no direction with respect to the frequency of such assessments.

The prices of medicines in the PMPRB-11 countries are affected by factors such as changes in currency exchange rates, differences in effective patent life / patent term restoration periods (CSP)[1], different comparators and significantly different regulatory requirements. The factors that affect prices in international price comparator countries are outside of rights holder's control. The fact that prices in the PMPRB-11 countries may decrease over time resulting in the Canadian price exceeding the HIP does not mean that there is patent abuse by the Canadian rights holder. Once a

[1] Please see Boehringer Ingelheim's submission dated September 11 2024 for further explanation of this topic.

price is deemed non-excessive based on HIP at the initial review, any attempt to decrease the price due to international price re-benchmarking is tantamount to price control and is in violation of the judicial guidance as provided in Merck Canada Inc. c. Procureur general du Canada.

In a similar vein, medicines that were launched prior to July 1 2022 ("existing medicines") and deemed non-excessive under the then legislation and Guidelines cannot be deemed excessive simply because the international basket has changed. Any such re-benchmarking may arbitrarily drive existing prices below non-excessive thresholds and would be an unconstitutional exercise of the PMPRB's excessive pricing mandate.[2]

In addition, the proposed annual review may trigger in-depth reviews and a lack of pricing predictability where rights holders may not be able to determine or anticipate a non excessive price at the time of product launch and throughout the product life cycle. Notwithstanding the draft guidelines acknowledgment that there may be instances where a Canadian price that exceeds the HIP may not be deemed excessive upon in-depth review, annual re-benchmarking creates unnecessary workload for the PMPRB and establishes an environment for future file-specific legal disputes. Business is loath to operate in an environment of uncertainty and unfortunately, uncertainty is exactly what is being proposed in the *Draft Guidelines for PMPRB Staff*. In fact, the document itself states that "… the guidelines are not intended to provide certainty …". Rights holders need certainty through the duration of patent life of new medicines as not having a price certainty would impact decisions to launch innovative and life saving therapies in Canada.
It appears that the draft guidelines are proposing that all future rulings from the Board should be unencumbered by any bright line rules and tests and rest simply on the Board's "discretion".

The draft guidance as written allows for International Price Comparison (IPC) review against the HIP if *"one or more list prices are filed for the medicine in any of the Schedule Countries"*. By not specifying that prices must be available in a representative proportion (number) of the Schedule Countries prior to IPC assessment, the Board is enabling the potential for significant non-intuitive variation in prices, where higher strengths or fixed dose combinations (FDC) have a lower list price than lower doses or a component of the FDC – for example, where multiple strengths/DINs are launched in Canada and due to varying regulatory restrictions some of those DINS are only available in a very limited number of very restrictive low priced countries e.g., Australia. This non-intuitive pricing can lead to increased or preferred use of the lower price medication which is not the recommended dose.

To this end, Boehringer Ingelheim proposes the following:

[2] See *Merck Canada c Canada*, 2022 QCCA 240 ¶197, 244.

A. Medicines Launched After July 1, 2022

- The price of a medicine be assessed against the HIP of the PMPRB-11 one time after its introduction into the Canadian market. The current practice of annual re-benchmarking should be stopped. It is our belief that the proposed annual re-benchmarking against prices in the PMPRB11 is a form of price control and therefore is in violation of the judicial guidance as provided in Merck Canada Inc. c. Procureur general du Canada; **and**
- The HIP assessment should take place when there are prices available for several of the PMPRB11 comparator countries [recommend six (6) or more]; and
- Annual assessments of these medicines may be performed to ensure that their list price has not been increased by an amount that is greater than allowable CPI.

B. Medicines Launched Before July 1, 2022

- Medicines launched before July 1 2022 and deemed compliant with the then international price referencing (against the PMPRB-7) should be grandfathered and not re-benchmarked against the PMPRB-11.
- Annual assessments of these medicines may be performed to ensure that their list price has not been increased by an amount that is greater than allowable CPI.

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