Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

BACKGROUNDER

PMPRB DRAFT GUIDELINES CONSULTATION

2022

Introduction

This document is intended to be read as a companion piece to the proposed Draft Guidelines. It supports readers' understanding of the Draft Guidelines by providing a plain language contextual explanation of key changes from previous iterations of the Guidelines. This document offers a high-level summary of these changes and is not intended to serve as an exhaustive treatment of the whole of the Draft Guidelines. It is being shared with the aim of fostering a more informed and productive consultation process. As is true of the Guidelines themselves, this Backgrounder is not in any way binding on the Board, Board Staff or rights holders.

In developing the Draft Guidelines, the Board took into account the feedback received from stakeholders and the public as part of recent consultations on the 2020 Guidelines and in response to the July 2022 Notice and Comment on the Interim Guidance. The Board was also mindful of the evolving nature of its operating environment and its continuing duty to use its consumer protection powers in a responsible and efficient manner.

Background

On April 14, 2022, the Minister of Health announced that the Government would proceed with amendments to the *Patented Medicine Regulations* ("Regulations") resulting in a newly constituted Schedule of comparator countries and reduced reporting requirements for medicines believed to be at the lowest risk of excessive pricing. The amended Regulations came into force on July 1, 2022.

In order to give effect to the Regulations and in furtherance of the Board's longstanding commitment to modernize and simplify its administrative framework, the PMPRB is proposing the new Draft Guidelines and is inviting its stakeholders and interested members of the public to provide feedback during a 60-day consultation period. In addition to the present document which explains certain key changes in the proposed Draft Guidelines, the PMPRB will be hosting a series of webinars for industry and the public. Requests from individual stakeholders to meet with the PMPRB to discuss the Draft Guidelines will be considered on a case-by-case basis during the consultation period. The deadline for providing written submissions is December 5, 2022.

The PMPRB remains committed to hearing from all Canadians who have an interest in and opinion on how it carries out its regulatory mandate and looks forward to receiving constructive and meaningful feedback from this consultation process with a view to issuing final Guidelines by end of year.

What's different about the Draft Guidelines?

Section 85 of the *Patent Act* ("Act") contemplates intervention by the Board only where the price of a patented medicine is found to be "excessive", which is determined based on a set of broadly expressed factors. Given the open-ended nature of the exercise contemplated under the Act, many of the core administrative concepts which give effect to the PMPRB's regulatory authority have been developed through the Guidelines, which the Board is authorized to make under subsection 96(4) of the Act, subject to consulting first with relevant stakeholders. While the Guidelines, by definition, do not have force of law, they have been held by the courts to be useful both for the PMPRB and the public and may legitimately inform the Board's reasoning in an excessive price hearing. Throughout the PMPRB's 35-year history, as the pharmaceutical market and regulatory landscape have evolved, so too have the Guidelines, with multiple substantive changes having taken place over time. The changes described below are a continuation of that decades-long effort.

Aside from referencing the new Schedule of 11 comparator countries ("PMPRB11"), these Draft Guidelines contain a number of substantive changes that are intended to streamline how Staff monitors and reviews patented medicine prices and reduce their administrative burden on rights holders. On the whole, the changes described below make for a more pragmatic, less prescriptive set of Guidelines that better resemble modern guidance documents issued by other federal regulators. In conceiving the changes explained below, the Board was cognizant of the fact that there is no one right way to carry out its regulatory responsibilities under the Act and Regulations. As with previous iterations of the Guidelines, the approach taken by Staff and the ultimate resolution of issues will depend on the particular circumstances of the matter in question. Final interpretation of the law is the responsibility of the Board (sitting as a Hearing Panel) and is subject to review by the courts.

1. Investigation criteria

Unlike current and previous iterations of the Guidelines, the Draft Guidelines do not separate patented medicines into different therapeutic categories and assign highly particularized excessive price tests that change from year to year. The Board believes that such an approach is not mandated by law and that it is possible to craft the bright-line guidance sought by rights holders while clearly delineating the respective roles and responsibilities of the Board and Staff. The adoption of the concept of "investigation criteria" in the Draft Guidelines is an alternative approach that serves to achieve both these objectives.

The proposed criteria that can give rise to an investigation are simple, straightforward and anchored in the section 85 factors at all times. For "new medicines", a concerted effort has been made in the Draft Guidelines to devise criteria that will only trigger an investigation when at least two of the factors are engaged whenever possible. This should significantly reduce the number of overall investigations and enable staff to focus resources on cases where the potential risk of excessive pricing is highest.

Under the Draft Guidelines, when the criteria are met and an investigation is opened, Staff will not presume the price of the medicine to be excessive. It is only after considering the totality of the circumstances surrounding the price of the medicine, through the lens of the section 85 factors, that Staff will close the investigation or recommend to the Chairperson that a hearing be commenced. As always, for reasons of administrative efficiency and resource optimization, where Staff is of the view that such a recommendation is warranted, it will work with the rights holder to achieve an outcome that avoids the need for litigation.

2. List Prices

Under the Draft Guidelines, the proposed investigation criteria apply to list prices only and will not fluctuate annually based on average transaction prices (ATP) the year before and a formula derived from CPI. This should make the potential triggering of an investigation more stable and predictable for rights holders. It also allows for more consistent and robust "apples-to-apples" price comparisons with the pricing information that is either filed by rights holders or is otherwise available to Staff from public sources, which mainly consists of domestic and international list prices for a medicine and/or its therapeutic comparators. Moreover, because list prices are by definition the highest prices that rights holders charge in the market, they are the most relevant prices for Staff to consider in the context of opening an investigation into potential excessive pricing. Under the Regulations, rights holders will continue to be required to file their ATP with the PMPRB, but Staff will only look at this information in the context of proposed undertakings by rights holders to offset potential excess revenues from the sale of a patented medicine that is subject to an investigation.

3. New and existing medicines

The Draft Guidelines distinguish between "existing" and "new" medicines and propose to apply less probing investigation criteria to the former. Existing medicines are defined as having received an NOC prior to the coming into force of the amended Regulations on July 1, 2022, and include line extensions of these same medicines. All other medicines are considered new medicines. This is a policy choice by the Board and a concession to rights holders whose expectations may have been raised by the Cost Benefit Analysis (CBA) that accompanied the publication of the original amendments to the Regulations. The Board is of the view that the misalignment of Canadian and international prices is best addressed by applying more probing investigation criteria to new medicines on a go forward basis.

It is important to note that this distinction is solely for administrative purposes and does not arise from a transitional provision in the Regulations, as was the case under the original amendments. As a result, from a legal standpoint, all patented medicines are subject to the same section 85 factors and have the same reporting obligations (with certain exceptions described below). Accordingly, once an investigation is opened, Staff will apply the same level of regulatory scrutiny to all medicines regardless of NOC date in determining whether to recommend the commencement of a hearing to the Chairperson.

4. Waiver of filing requirements for medicines believed to be at lower risk of excessive pricing

Under the amended Regulations, patented over-the-counter (OTC) medicines, certain non-prescription controlled substances, generic and veterinary medicines are not required to file pricing and other information with the PMPRB unless specifically requested to do so by the PMPRB. The Draft Guidelines propose to operationalize this by only opening an investigation in the event that a complaint is received in respect of one of these types of products. In response to feedback from its consultation on the 2020 Guidelines, the Board has opted to expand this list of products for administrative purposes to include biosimilars and vaccines, as these are also thought to be at lower risk of excessive pricing. Biosimilars are, in many ways, subject to similar market conditions as generic medicines. Regulating biosimilars on a complaints-basis is also consistent with the Canadian Agency for Drugs and Technologies in Health's (CADTH's) recent decision to no longer review biosimilars for cost effectiveness in order to simplify and streamline market access for these products. As for vaccines, most are subject to a public tendering process designed to award the contract to the bidder with the best value proposition. It should be noted that all the foregoing products remain subject to the Board's jurisdiction provided they are patented and a complaint in respect of any one of them will automatically result in the opening of an investigation, which may or may not result in a recommendation to commence an excessive price hearing.