Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

PMPRB GUIDELINES SCOPING PAPER

High Level Overview of Potential New Framework

CGI CONSULTATION PHASE

Canada

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INTRODUCTION

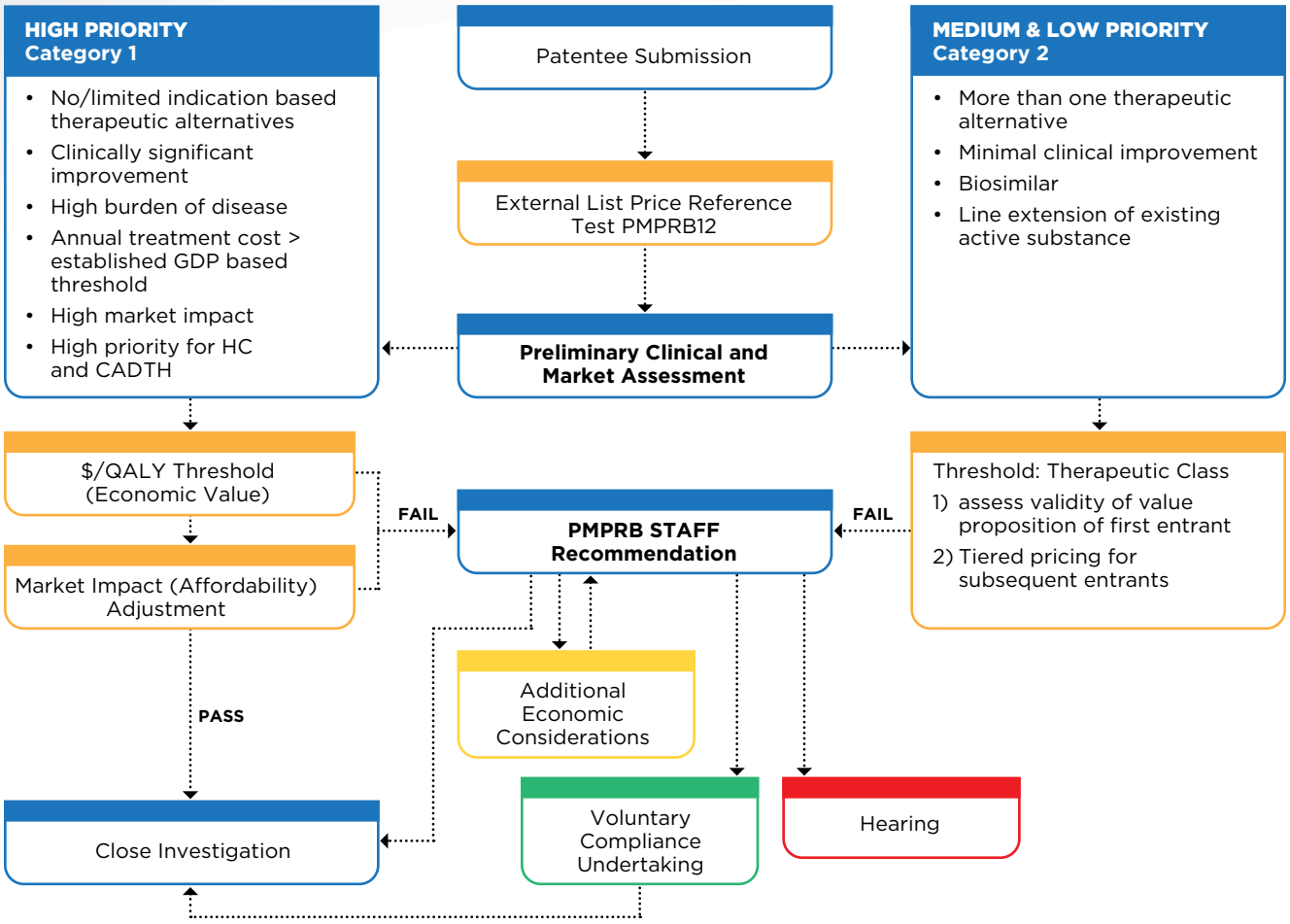
This scoping paper is intended to be read in conjunction with proposed amendments to the *Patented Medicines Regulations* ("Regulations"), and accompanying Regulatory Impact Analysis Statement (RIAS), which were pre-published in the December 2nd, 2017 issue of the Canada Gazette, Part I. Its purpose is to provide stakeholders and interested members of the public with an outline of the PMPRB's preliminary thoughts on how best to operationalize the proposed changes to the Regulations, through non-binding Guidelines as contemplated by s.96 of the *Patent Act*, within the context of the existing and proposed legislation and the PMPRB's ongoing efforts at reform. It is hoped that this document will serve as a catalyst for a more informed, focussed and productive consultation process on framework modernization, with a view to having new Guidelines in place by early 2019. This document is not to be viewed as a definitive interpretation of the current or proposed legislation or of the RIAS for the proposed amendments by the PMPRB, is not the Government's expression of policy intent or an official part of the Canada Gazette I (CGI) consultation, and is not intended to bind the PMPRB or the Government in the application and interpretation of legislation. The PMPRB will officially consult on a revised set of proposed Guidelines in the spring of 2018.

THE NEW FRAMEWORK

As an expert economic regulatory body, the PMPRB must ensure that its new framework is grounded in sound and prevailing economic theory. In conceiving the mechanics of that framework, the PMPRB was mindful of the Minister of Health's stated policy rationale for the proposed regulatory amendments and of the overarching purpose of the current and proposed legislation. The PMPRB also sought to give effect to areas of stakeholder agreement that emerged from the recent Guidelines modernization consultation. Accordingly, to the extent possible, the framework envisaged by the PMPRB employs economically-derived, bright line tests to yield meaningful ceiling prices that are foreseeable to patentees. As before, the new Guidelines are proffered as rules of general application which serve as a mechanism for determining a rough estimate of where the line between potential non-excessive prices and potential excessive prices should be drawn by PMPRB staff. The objective of the Guidelines is to enable the calculation of a national ceiling price above which it would be unreasonable for any consumer in Canada to pay, not an ideal price for each payer based on their individual ability and willingness to pay.

While the details of the framework remain to be worked out through consultation, its basic structure can be described as a risk-based approach to pricing review that is broken down into five main parts, as illustrated in the following schematic and discussed in more detail below.

PROPOSED PRICE REVIEW SCHEMATIC*



*For discussion purposes only, not intended to bind or limit the PMPRB or the Government in the application and interpretation of legislation

Part I: Interim international price reference test

At introduction, all new drugs would first be subject to an interim price test based on the list price of a new drug in Canada against the list price in the proposed PMPRB12 basket of countries. Domestic and international list prices in today's environment of confidential discounts and rebates represent the starting point of a price negotiation rather than a true reflection of actual price paid in the market place. In this context, the PMPRB would look at how the proposed price in Canada compares to public list prices in other markets. If the price in Canada exceeds the median of the PMPRB12, it would be considered potentially excessive.

Part II: Screening

The second part of the framework consists of a screening phase which would classify new patented drugs as either high or low priority based on their anticipated impact on Canadian consumers, including individual patients and institutional payers (e.g., public and private drug plans). At this stage in the process, the PMPRB would consider whether the drug is first in class, has few or no therapeutic alternatives, provides significant therapeutic improvement over existing treatment options, is indicated for a condition that has a high prevalence in Canada, is a high cost drug (i.e. an average annual cost higher than a GDP-based threshold) or is classified as a high priority drug by other agencies/regulators in the health care system (such as the Canadian Agency for Drugs and Technologies in Health (CADTH) or Health Canada) because of unmet medical need. Drugs that appear to be high priority based on these screening factors would be subject to automatic investigation and a comprehensive review to determine whether their price is potentially excessive.

Part III: High priority drugs

Once a drug is assessed as high priority, the third part of the new framework would see the PMPRB apply a two-part test for evaluating potential excessivity[1].

The first part of the test would assess the incremental cost per quality-adjusted life year (QALY) of the drug, as determined by CADTH's health technology assessment process, against an explicit cost effectiveness threshold. The threshold would be based on the opportunity cost associated with displacing the least cost effective health technology in the Canadian health system, otherwise understood as the marginal cost of a QALY, as calculated by expert health economists and revised periodically to reflect changing market conditions. Drugs that prolong life or provide significant QALY gains could be subject to a more generous threshold, as Canadian payers have demonstrated a higher willingness to pay for these types of drugs.

The second part of the test would assess whether a drug that meets the cost effectiveness threshold should have its price further adjusted because of its expected impact on payers within the first three to five years from launch (assuming appropriate clinical utilization and no rationing of care). This test would consider the anticipated market size of the new drug against GDP growth, with the latter serving as a rough proxy for how much Canadian consumers can afford to pay for the new patented drugs that come to market on an annual basis. The test could also be used to allow a price adjustment upward in instances where a drug has a very high opportunity cost but very small market impact due to the extreme rarity of the condition it is indicated to treat.

[1] The test addresses current factors that the PMPRB must consider under s.85 of the *Patent Act* as well as the new factors that are identified in the proposed amendments to the Regulations published on December 2, 2017.

If the price fails this two-part test, the patentee would be provided with an opportunity to explain why the price of its drug is not excessive having regard to the cost of making or marketing it or such other economic factors it believes are relevant in the circumstances. Patentees would be permitted to provide confidential commercial information in support of their position, including true prices in the PMPRB12 and proposed non-transparent rebates and discounts to direct and indirect payers in Canada. If the outcome of the above process is a determination that the price of the drug is potentially excessive:

- Its public ceiling price would continue to be set by international price referencing; but
- the ceiling price resulting from the application of the two-part test would be kept confidential.

Patentees will be required to report price and revenue information to the PMPRB net of direct or indirect third party discounts or rebates. This will ensure that the PMPRB is fully informed of the actual prices for patented drugs in Canada but also enable patentees to comply with much lower ceiling prices under the new framework.

Part IV: Medium and low priority drugs

The fourth part of the new framework would apply to medium and low priority drugs. Drugs in this category would be expected to have a minimum number of therapeutic alternatives and offer little or no therapeutic improvement over the standard of care. Drugs considered to be medium priority would be subject to the same initial price test as high priority drugs, such that they would be considered potentially excessive if their public list price is above the median of public list prices in the PMPRB12 countries. For this class of drugs, the PMPRB could employ a revised therapeutic class comparison test that requires each successive entrant to reduce its price relative to the price of the drug that preceded it. Again, patentees would be provided with the opportunity to explain why a higher price is justified based on the same economic factors that are considered relevant for high priority drugs.

Drugs categorized as low priority, because of the presence of a significant number of therapeutic alternatives in the market and/or generic competition, would not be subject to an introductory or ongoing s.85 analysis and would be investigated on a complaints basis only.

Part V: Re-benching

The fifth and final part of the new framework would involve the periodic "re-benching" of drugs to ensure that previous determinations of potential excessive pricing and/or price ceilings remain relevant in light of new indications (resulting in a change of market size) or changes in market conditions. Depending on the nature of the change, the re-benching process could result in a decrease or increase in ceiling price.

CONCLUSION

If passed in their current form, the proposed amendments would allow the PMPRB to move to a risk-based framework that scrutinizes drugs with the greatest potential for excessive pricing and takes into account both their value to, and financial impact on, consumers in the health system when setting ceiling prices. This would constitute a paradigm shift in how the PMPRB regulates patented drug prices but would not depart from or expand on its original mandate.

By explicitly requiring the PMPRB to consider the new proposed factors, policy makers have recognized that price alone does not provide sufficient context by which to evaluate excessive pricing in the current climate. Specifically, price divorced from value, cost and affordability does not capture key inputs in determining what the impact of a drug will be on payers or on total population health. These are critical considerations in an era marked by increasingly constrained health budget envelopes, an aging population and an ever increasing number of drugs with annual average treatment costs in the hundreds of thousands of dollars.

It should be emphasized that the above described framework is only notional at this stage and may change as a result of any differences between the proposed amendments and the final Regulations or in response to stakeholder feedback from PMPRB-led consultations on Guideline reform.

NEXT STEPS

In the coming weeks, Health Canada and the PMPRB will be hosting multi-stakeholder webinars where the department will address the proposed regulatory amendments and the PMPRB will address the changes discussed in this scoping paper. The PMPRB will also be making Guideline reform the focus of its upcoming annual outreach sessions for patentees to be held in January of 2018. It is expected that a first draft of the PMPRB's new Guidelines will be made public in the spring of 2018, with technical roundtables to be scheduled shortly thereafter. However, at this stage of the process, the PMPRB is specifically encouraging stakeholders to reflect on the following questions in order to prepare for upcoming consultations on a revised set of proposed Guidelines:

1. What considerations should PMPRB use in screening drugs for high priority?
2. To what extent should low priority drugs be scrutinized?
3. How should a cost effectiveness threshold be established?
4. Should the application of a threshold be subject to further adjustment depending on market size considerations?
5. How should re-benching work and when should it occur (and to what drugs)?
6. What price tests should the PMPRB apply to the new PMPRB12?
7. How should the PMPRB make use of confidential third party pricing information?

FURTHER INFORMATION

Questions or clarifications on the content of this document can be submitted by email, letter mail or fax to:

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