



Patented Medicine  
Prices  
Review Board  
*Since 1987*

The Patented Medicine Prices Review Board is a quasi-judicial tribunal with the mandate to ensure that manufacturers' prices of patented medicines sold in Canada are not excessive.

**PMPRB**

# Results

of the March 2009  
**Consultation**  
and the Board's revised  
**Excessive Price**  
**Guidelines**

June 2009

If you wish to know more about the PMPRB,  
please contact us at our toll-free number,  
1 877-861-2350, or consult our Web site.

Canada

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# Introduction and Purpose

On March 26, 2009, the Patented Medicine Prices Review Board (PMPRB) released a draft revised version of its Compendium of Policies, Guidelines and Procedures (Compendium) for stakeholder notice and comment. We would like to thank all those who provided feedback and input in this final round of public consultations. The Guidelines review exercise covered a broad range of issues, each with a significant level of complexity, and the Board appreciates the considerable effort stakeholders have taken to be active participants in the consultations over the last four years.

The consultation process for the Guidelines review exercise is now complete. We have considered all of the submissions provided by stakeholders and have made our final decisions on the issues under consultation. We are now releasing the new Compendium, which will come into effect on January 1, 2010.

As a result of the last round of consultations, some aspects of the Compendium have been modified. This document provides an overview of the issues that were under consultation, a summary of the feedback received from stakeholders, the Board's position on the issue, as well as a description of what modifications were made.

Board Staff has organized initial outreach sessions about the new Compendium for the benefit of patentees and to answer any questions they may have on the implications of the revised Guidelines. The first outreach session will take place in Toronto on June 17, 2009, and the second will take place in Montreal on June 18, 2009. Additional details on these initial outreach sessions have been sent to patentees.

Once again, we would like to take the opportunity to thank everyone who participated in the Guidelines review exercise. Your contribution to the consultation process has been immeasurable and you have our sincere appreciation.



Brien G. Benoit, MD  
Chairman

## Board Positions on Revisions to the Compendium of Policies, Guidelines and Procedures

The majority of the issues discussed in the following section were previously discussed as part of the March 2009 consultation, except for a new overarching issue raised by stakeholders on the selection of prices for drug products used for comparison purposes. This new issue will be discussed first, followed by the remaining issues that are addressed in the same order as previously listed in the Notice and Comment document of March 2009.

For background documents on previous consultations, please refer to the "Consultations" section of the Board's Web site.<sup>1</sup>

### Selection of Prices for Drug Products Used for Comparison Purposes

In the previous revised draft Guidelines, the descriptions of the Therapeutic Class Comparison (TCC) test and the Reasonable Relationship (RR) test stated the following:

*If the drug product used for comparison purposes is patented and sold by the same patentee introducing the new patented drug product, the price for the drug product used for comparison purposes will be the National Average Transaction Price of that drug product.*

*Where the drug products used for comparison purposes are themselves patented but sold by a different patentee than the patentee introducing the new patented drug product, Board Staff will use public sources for prices for the drug products used for comparison purposes. Board Staff will find the public price that is sufficiently close to the National Non-Excessive Average Price of the patented drug product used for comparison purposes.*

### Stakeholder Feedback

Industry stakeholders raised the following concerns about the above paragraphs:

- Using a price that is "sufficiently close to the National Non-Excessive Average Price" may not sufficiently protect confidential pricing information;
- The sources of price information used to determine the price of a drug product for comparison purposes are not transparent, and since the National Non-Excessive Average Price is confidential, patentees will not easily be able to determine if the introductory prices of new patented drug products would be excessive;
- When the price of a new drug product is determined by the price of an existing drug product's National Non-Excessive Average Price, the price of the existing drug product could be lower due to the inclusion of benefits, which could lower the price of the new drug product at introduction; and
- A perceived "double standard" was identified, in that a drug product that is patented and sold by the same patentee is compared against different prices than when a drug product for comparison purposes is sold by a different patentee.

### Board Position

The Board is striving for transparency in the scientific and price review processes in order to ensure fair and predictable application of the Guidelines. It agrees that greater transparency could be achieved if patentees knew in advance the sources of pricing information Board Staff would be using during the price review of a new patented drug product. To this end, the Board has decided to specify a list of publicly available sources of price information in the Guidelines, from which Board Staff would use the lowest public price in the case of both when the comparator drug is sold by the same patentee or a different patentee. If there are no prices for a comparator drug in any of these sources, Board Staff may need to look for other sources.

<sup>1</sup> <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=568>

## Regulatory Mandate Statement

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In the March 2009 draft revised Guidelines, the Board made a revision to its regulatory mandate statement, which read:

*To ensure that the prices charged by patentees for patented medicines sold in Canada are not excessive, consistent with the interests of consumers and the Canadian health care system.*

### Stakeholder Feedback

Industry stakeholders voiced concern, indicating that the *Patent Act* contains no reference to consumer protection or interests, or to Canadian health care, and hence no such statement to this effect should be added to the mandate.

### Board Position

The Board takes the position that the PMPRB was created in 1987 with the interests of Canadians and the Canadian health care system in mind. It acknowledges, however, that no such language exists in the *Patent Act*.

The Board has decided that the mandate statements in the Guidelines, for both the regulatory and reporting roles of the PMPRB, should mirror the language in the *Patent Act*. The qualifying statements as to the rationale for the work of the PMPRB will be included in the Board Origins section of the Legal Framework.

## Confidentiality of Information Provided to the PMPRB

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In the March 2009 draft revised Guidelines, the Board took the view that any information submitted by a patentee to the PMPRB that is in the public domain will not be considered privileged under subsection 87(1) of the *Patent Act*. Further, although it has been the Board's practice to not publish the publicly available ex-factory prices of a patented medicine in Canada and other countries listed in the *Patented Medicines Regulations* (Form 2, Block 5) without the patentee's consent, since the Form 2, Block 5 information is by definition required to be publicly available, it will no longer be considered privileged information under subsection 87(1) of the *Patent Act*.

### Stakeholder Feedback

While some industry stakeholders acknowledged that the PMPRB has the right to publish pricing information which is publicly available, many contended that information provided under Form 2, Block 5 should remain privileged. Some industry stakeholders cited the rationale for keeping Form 2, Block 5 privileged was that the international price information provided to the PMPRB was not always publicly available.

### Board Position

The Board would like to remind patentees that paragraph (4)(f)(iii) of the *Patented Medicines Regulations* directs patentees to only provide publicly available ex-factory prices when completing Form 2, Block 5.

## **Modification of Terminology Regarding the “Maximum Non-Excessive Price”**

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In the March 2009 draft revised Guidelines, the Board proposed new terms to provide greater clarity to the price review process. For new patented drug products the term “Introductory Maximum Non-Excessive Price” was replaced by the “Maximum Average Potential Price”, and for existing patented drug products the term “Maximum Non-Excessive Price” was replaced by “Non-Excessive Average Price”.

### **Stakeholder Feedback**

Few stakeholders commented on the change in terminology. It was expressed by some that the new terms are clearer than the previous terms, but how they will be used in the various price tests requires clarification prior to implementation.

### **Board Position**

The Board has decided to adopt the new terms.

## **Publication of the CPI-Inflated Maximum Average Potential Price**

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In the Notice and Comment document of March 2009, a proposal was put forward to publish both the Maximum Average Potential Price, and this price grown by CPI on a cumulative basis every year. It was noted however, that while the Maximum Average Potential Price at introduction is a price that no market can exceed, the Consumer Price Index (CPI)-inflated Maximum Average Potential Price would have no regulatory significance.

### **Stakeholder Feedback**

Most stakeholder comments were silent on the proposal, but those who did comment questioned the utility of publishing this pricing information, remarking that it has no practical value.

### **Board Position**

The Board has decided not to publish the Maximum Average Potential Price inflated by CPI. It will however continue to publish the Maximum Average Potential Price at introduction as part of the new medicine summary reports for new active substances.

## Levels of Therapeutic Improvement

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In the Notice and Comment document of March 2009, the Board informed stakeholders that it was adopting the four new levels of therapeutic improvement as put forward in the earlier Notice and Comment document of August 2008. The Board also adopted the proposed changes regarding the primary and secondary factors for determining levels of therapeutic improvement put forward in August 2008, including the restriction that secondary factors can only result in the level of therapeutic improvement being assessed at up to the level of “moderate” therapeutic improvement.

### Stakeholder Feedback

While stakeholders were supportive of the new levels of therapeutic improvement, industry stakeholders took issue with the Board's decision to limit the use of secondary factors in assessing the level of therapeutic improvement. Industry stakeholders felt secondary factors should allow the level of therapeutic improvement to be assessed beyond the “moderate” level, and that the Board's decision was at odds with the recommendation of the PMPRB's Working Group on Therapeutic Improvement.

### Board Position

It is still the Board's position that secondary factors do not carry sufficient weight to move the level of therapeutic improvement from “moderate” to “substantial improvement”, which should only be possible through consideration of primary factors.

## The Reasonable Relationship (RR) Test

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In the Notice and Comment document of August 2008, the Board had proposed a modification to the third part of the Reasonable Relationship test, such that the price of a new lower strength drug product would be proportional to that of a higher strength. During the consultation period that followed, industry stakeholders took exception to the modification, citing that it would create a disincentive to making available drug products used in “titration dosing”.

The Board took this feedback under advisement and in the Notice and Comment document of March 2009, the Board proposed to revert back to the original intent and methodology of this test. The Board also put forward the following: additional language to clarify when and how the RR test would be conducted; a modification to allow the second part of the RR test to recognize the possibility of level pricing per unit for multiple strengths of a patented drug product (i.e., zero slope); and a change to address the issue of a possible negative price due to a negative Y-intercept.

### Stakeholder Feedback

Some non-industry stakeholders urged the PMPRB to adopt the proposal for proportional pricing put forward in the August 2008 Notice and Comment document.

### Board Position

The Board has decided to adopt all of the proposed changes to the RR test put forward in the Notice and Comment document of March 2009.

## Limited Comparators for Patented Generic Drug Products

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In the Notice and Comment document of March 2009, the Board confirmed its decision to adopt modified Guidelines for patented generic drug products, which would limit the comparators to only the reference (bioequivalent) or licensing brand's drug product.

### Stakeholder Feedback

Feedback from the generic industry association supported the Board's decision. No other comments were received from other stakeholders.

### Board Position

The Board is confirming its decision to adopt these modified Guidelines.

## Highest International Price Comparison (HIPC) Test

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In the Notice and Comment document of March 2009, the Board decided that a specific exemption to the HIPC test would not be adopted for certain patented generic drug products. The Board indicated that fairness is a key principle in price regulation and that all patentees should face the same Highest International Price Comparison constraint.

### Stakeholder Feedback

Representatives of the generic pharmaceutical industry indicated their disappointment with the PMPRB's decision, re-iterating their position that the HIPC test is unworkable for patented generics, particularly when applied to price reviews at the level of any market.

### Board Position

In order to ensure a consistent and fair application of the HIPC test for all patentees, but recognizing the nature of generic drug prices and rebates, the Board has decided that the HIPC test will only be conducted at the national level, for the pharmacy and hospital customer classes, and for each province and territory. The HIPC test will not be applied to the wholesaler class of customer. This approach will apply to all patented drug products.

## International Therapeutic Class Comparison (ITCC) Test

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In the Notice and Comment document of March 2009, the Board outlined its proposal for Guidelines on the International Therapeutic Class Comparison test in terms of which selected generic drugs would be included (i.e., only generics that are sold both in Canada and in a comparator country by the same patentee).

### Stakeholder Feedback

Stakeholder feedback from industry representatives focussed on the Board's decision to allow the inclusion of certain generic drug products in the ITCC test. The Board was urged to consider the exclusion of all generic drug products in the ITCC test, consistent with the recommendations of the Working Group on International Therapeutic Class Comparison, when any statistical value other than the maximum of the ITCC test is used.

## Board Position

The Board's position is that the drug products used for comparison purposes in the ITCC should mirror those used in the domestic Therapeutic Class Comparison test. The Board does not support the complete exclusion of generic drug products from the ITCC test. As the domestic Therapeutic Class Comparison includes generic drug products, the Board believes it to be appropriate to include in the ITCC test only those generics sold by companies that also sell the same generic drug product in Canada.

The Board has therefore decided that the Guidelines on the ITCC test will be adopted as written in the March 2009 Notice and Comment document. It should be noted that the ITCC test is not a pivotal price test, but rather may provide useful information in the context of an investigation.

## Any Market Price Reviews

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In the Notice and Comment document of March 2009, the Board confirmed its proposed approach for undertaking price reviews at the level of any market, but added a proposal to review the price of a drug product in each province and territory at introduction. The Board also put forward a proposal regarding the appropriate methodology for the calculation of excessive revenues, which would be based on the average price across all markets in Canada (i.e., the National Average Transaction Price).

## Stakeholder Feedback

Industry stakeholders continued to state that the evidence does not support the need to regulate at this level, and it will result in significant regulatory burden for patentees. Industry stakeholders did express support for the Board's decision to calculate excess revenues based on the average price across all markets. Those non-industry stakeholders that responded supported the Board's proposal for any market price reviews.

## Board Position

The Board reiterates its position that some level of market-specific price review is part of its statutory mandate. In addition, as the Board will not be requiring any additional pricing information beyond what is currently required by patentees in the *Patented Medicines Regulations*, it does not support the contention that any market price review will result in significant undue regulatory burden for patentees. In addition, stakeholders are reminded that for existing drug products, any market price reviews will not be undertaken on a regular basis. Board Staff will only be doing price reviews at the level of any market for existing drug products when the investigation criteria are triggered.

The Board has decided to adopt the approach to any market price review and the calculation of excess revenue as written in the Notice and Comment document of March 2009.

## Re-setting the Non-Excessive Average Price after Introduction

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In the previous draft revised Guidelines, the Board proposed the following paragraph be included:

*"The Board recognizes that there may be cost of making and marketing arguments, whereby it may be appropriate to adjust the Non-Excessive Average Price of a patented drug product (e.g., once a Notice of Compliance has been obtained and the drug product was first sold on a compassionate basis as an Investigational New Drug, through a Clinical Trial Application or under the Special Access Programme)."*

### Stakeholder Feedback

Industry stakeholders took issue with the proposed paragraph, citing reasons beyond the cost of making and marketing that should be considered in re-setting the Non-Excessive Average Price after introduction. It was indicated that limiting re-setting to just the cost of making and marketing would result in a disincentive to offering benefits/discounts on drug products that have not yet received a Notice of Compliance.

### Board Position

The Board maintains the position that simply receiving a Notice of Compliance in and of itself is not sufficient cause to trigger consideration of re-setting the Non-Excessive Average Price.

The Board has decided to adopt the approach to re-setting as written in the Notice and Comment document of March 2009.

## Recognizing Benefits (DIP Methodology)

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In the August 2008 Notice and Comment document, the Board proposed what has come to be known as the "DIP Methodology" as a possible alternative to the application of the CPI-Adjustment Methodology when an apparent excessive price was due solely to the termination or reduction in a benefit.

In the Notice and Comment document of March 2009, the Board put forward additional clarification on the DIP Methodology.

### Stakeholder Feedback

Industry stakeholders primarily commented that the DIP Methodology continues to be a disincentive to the provision of benefits. It was felt that once a benefit to a market ends, limiting the price increase to the previous highest Average Transaction Price in that market prevents patentees from taking price increases based on the CPI that would have been allowed. The Board was urged to modify the DIP Methodology to increase the price of an affected market up to the highest previous Average Transaction Price of that market increased by the allowable CPI during the period of the benefit. It was also felt that the DIP Methodology is overly complicated and that it will increase the workload of patentees and Board Staff.

### Board Position

The Board has decided that, subject to the evidence requirements contained in the Guidelines, a market employing the DIP Methodology may potentially rebound up to the highest Non-Excessive Average Price of another class of customer (or province/territory).

Patentees seeking to employ the DIP Methodology in markets where some benefits end but others are still ongoing would be limited to a price commensurate with the remaining benefits.

The Board has decided to modify the DIP Methodology.

# Use of Patented and Non-Patented Drug Products in the Price Tests

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In the Notice and Comment document of March 2009, the Board put forward a Policy on the Use of Patented and Non-Patented Drug Products in the Price Tests in order to provide greater clarity to stakeholders on the current practices of Board Staff.

## Stakeholder Feedback

No comments on this policy were provided by stakeholders.

## Board Position

The Board has decided to adopt the Policy on the Use of Patented and Non-Patented Drug Products in the Price Tests as written in the Notice and Comment document of March 2009.

# Offset of Excess Revenues

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In the Notice and Comment document of March 2009, the Board put forward a Policy and a consolidated Schedule on the Offset of Excess Revenues, which included the following:

- To offset excess revenues via a price reduction, the average price of a patented drug product will only be considered to have been reduced if it is below the previous year's Non-Excessive Average Price; not taking an allowable price increase will not be considered for purposes of offsetting excess revenues.
- Excess revenue balances below the amount sufficient to trigger the investigation criteria that are carried for six consecutive six-month reporting periods (3 years) will be expected to be offset through a Voluntary Compliance Undertaking. Failing this, Board Staff will refer the matter to the Chairperson.
- When a price reduction below the Non-Excessive Average Price is taken in one or more markets specifically to offset excess revenues, following the repayment of excess revenues, the Average Transaction Prices in those markets may return in the next reporting period up to the Market-Specific Non-Excessive Average Prices prior to the price reduction.

## Stakeholder Feedback

Industry stakeholders felt that previous approaches to offsetting excess revenues were acceptable, and that the new policy is punitive. It was also expressed that seeking the offset of excess revenues below the investigation criteria did not correctly allocate scarce PMPRB resources.

## Board Position

Excess revenues generated by a patentee reflect the fact that customers on average were paying a price that appeared excessive. The Board's position is that to offset this excess revenue through a price reduction, the average price of a patented drug product will only be considered to have been reduced if it is below the previous year's Non-Excessive Average Price. The Board also maintains the position that excess revenues below the amount sufficient to trigger the investigation criteria that are carried for six consecutive six-month reporting periods (3 years) will be expected to be offset through a Voluntary Compliance Undertaking.

The Board has decided to adopt the Policy on the Offset of Excess Revenues as written in the Notice and Comment document of March 2009.

## Policy for When a Price May be Considered Excessive

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In the Notice and Comment document of March 2009, the Board included a Policy for When a Price May be Considered Excessive. Within the Policy, paragraph 5.2 stated the following:

*If the National Average Transaction Price exceeds the Maximum Average Potential Price or National Non-Excessive Average Price, but does not trigger the criteria for commencing an investigation (see Schedule 11), the patentee will be notified and the patented drug product will be reported on the PMPRB Web site as "Appears Excessive".*

### Stakeholder Feedback

Some industry stakeholders took issue with the policy statement, and felt that stating on the PMPRB's Web site that a drug product "appears excessive" is misleading and automatically presumes that a price is excessive, especially when it has yet to trigger the investigation criteria.

### Board Position

The Board has decided to replace the designation "appears excessive" with the new designation "Does Not Trigger Investigation". The Board believes this designation more accurately reflects the compliance status of a drug product, and does not allude to the presumption of excessive pricing.