

**Canada's Research-Based Pharmaceutical Companies
(Rx&D)**

***Response to PMPRB "Price Increases for Patented
Medicines: Discussion Paper"***



Rx&D member companies employ over 22,000 Canadians across the country including 4,000 researchers. In addition, through partnerships between Rx&D member companies and universities, hospitals and research institutes across Canada, approximately 6,000 researchers are working to discover new medicines. Through matched funding with the CIHR, the Rx&D Health Research Foundation Awards Program has provided over \$23 million in funding to more than 1,439 researchers across Canada since 1987.

May 9, 2005

Introduction

The Patented Medicine Prices Review Board (the PMPRB) has asked stakeholders to participate in a discussion regarding the board's "Excessive Price Guidelines", (the guidelines) relating to price increases. The consultation is being aided by a discussion paper entitled **Price Increases for Patented Medicines** issued in March 2005¹.

According to the discussion paper, the PMPRB was advised in 2004 that several manufacturers of patented medicines had informed customers of proposed price increases. Even though the paper acknowledges that the price increases appeared to be consistent with the PMPRB guidelines, the Board apparently has a concern that it may be seeing the beginning of a change in trends related to patented medicine prices.

The paper insists that the PMPRB is not making specific proposals regarding price increases, but rather, it is asking questions in the context of its mandate under the *Patent Act* to ensure that prices of patented medicines in Canada are not excessive. However, it appears clear from the tone of the paper that the board is considering a change to its current guidelines. In the discussion paper, stakeholders are asked to consider, and provide feedback by May 9, 2005 regarding, the following five questions:

1. Should the PMPRB's guidelines continue to allow for automatic, (i.e. without prior approval) price increases?
2. Are there considerations other than, or in addition to, the CPI that should be used to review price increases?
3. How often should price increases occur? (e.g. every year, once every 3-5 years, only after a certain introductory period, when justified)
4. If justification is required, what criteria should be considered?
5. Given that the CPI is established in the *Patent Act* as a factor to be considered by the PMPRB, do you have any comments on its appropriate application in future guidelines?

In addition, stakeholders are asked to consider three proposed frameworks representing different regulatory approaches to price increases as follows:

1. The current system in which patentees are allowed to take an automatic price increase in a given period up to a pre-determined maximum, with price reviews taking place after the fact.
2. A new scenario in which patentees would be required to inform the PMPRB in advance of any price increase, allowing a review of the proposed price increase before it is implemented to ensure that the new price is within the guidelines.
3. A new requirement in which patentees would apply, in advance, for a price increase and also would be required to provide justification for the proposed increase and the extent of the increase. Thereafter, the PMPRB would make a determination regarding the appropriateness of the increase and the extent of the allowable increase, (if any) up to a non-excessive maximum.

¹ Price Increases for Patented Medicines: Discussion Paper, March 2005 <http://www.pmprb-cepmb.gc.ca/CMFiles/notice-Mar05-E15GGG-392005-5938.pdf>

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Canada's Research-Based Pharmaceutical Companies (Rx&D) welcomes the opportunity to participate in this discussion, notably to bring light to the larger context in which such a discussion should take place.

However, the association wishes as well to state clearly that it fails to appreciate the rationale for a formal review of the guidelines at this time given the lack of any evidence that suggests recent price increases might lead to a significant alteration in long-standing trends related to patented pharmaceutical pricing.

Following an executive summary and brief introduction, Rx&D's submission will consider the three hypothetical regulatory frameworks put forward in the discussion paper and then, to proceed to contemplate the five specific questions outlined above with regard to PMPRB's guidelines.

Executive Summary

- *Any review of the PMPRB's guidelines with respect to price increases should be conducted as part of a sectoral review, taking into account not only the PMPRB price review factors, but the entire pharmaceutical policy and regulatory environment including regulatory approval, intellectual property protection, investment, research & development, health care funding, etc.*
 - *Any new policies must seek to ensure fair pricing and access to affordable medicines, as well as promote the trade and industrial development objectives of pharmaceutical patent legislation.*
- *It is Rx&D's view that there is no public policy justification for further limitations on price increases related to patented medicines. Indeed, there should be greater pricing flexibility for patented medicines to ensure pricing is responsive to market conditions, patients have timely access to therapies and that there are sufficient funds available for continued R&D.*
- *Regarding the proposed alternative Frameworks 2 and 3, Rx&D must point out that, clearly, they would increase the regulatory burden on patentees unnecessarily and inhibit the efficiency of the price review process, without offering any benefit to consumers. More importantly, the Board has no statutory authority to pursue these initiatives under the Patent Act given that the act limits the ability to impose any requirements for regulatory review before prices are implemented in the marketplace.*
- *The PMPRB has no authority under the Patent Act to seek prior approval of price increases.*
- *As the PMPRB has noted, price increases over the past decade have been infrequent and well within the limits of the Consumer Price Index (CPI).*
- *The application of the existing CPI Guideline is too restrictive. Price increases up to CPI are by definition not excessive - price increases beyond CPI should only be considered excessive after consideration of all factors listed in the Act.*
- *Rx&D takes the view that justification of price increases should be required only after the fact, (i.e., not in advance) and, only in cases where the price increase exceeded the CPI by a significant margin and at least one other factor which may be used to determine if a price is excessive.*
- *Rx&D believes that patentees' introductory prices should be compared with CPI-adjusted prices of comparator medicines when conducting a therapeutic class comparison test.*

Introduction: The Importance of Balance

Medicines are one of the most cost-effective interventions in our health care system. A restrictive pharmaceutical market limits choice and access to new treatments.

Rx&D believes that any review of the PMPRB's guidelines with respect to price increases should be conducted as part of a comprehensive sectoral policy review, taking into account the entire pharmaceutical policy environment. Furthermore, any new pricing policies must seek to ensure fair pricing and access to affordable medicines, as well as promote the trade and industrial development objectives of pharmaceutical patent legislation.

The Patented Medicine Prices Review Board's (PMPRB) statutory mandate (i.e. to ensure that the prices of patented medicines are not excessive) is built around the notion of abuse of patent. That is to say that the price of a patented medicine should only be considered 'excessive' if it represents a clear abuse of the market exclusivity afforded by the patent(s) pertaining to the medicine. As the PMPRB has noted, price increases of patented medicines over the past decade have been infrequent and well within the limits of the CPI.

The PMPRB has asked stakeholders to participate in a discussion of the PMPRB's Excessive Price Guidelines relating to price increases.

In Appendix I to the *Price Increases for Patented Medicines: Discussion Paper*² issued in March 2005, the PMPRB states that the 1987 amendments to the patent legislation were drafted around "five essential pillars":

- Intellectual property
- Industrial benefits
- Canada's multilateral relations
- Consumer protection
- Health care

Indeed, when the *Patent Act* was amended in 1987, Parliament's intention was to foster increased pharmaceutical research and development in Canada while at the same time, ensuring that prices of patented medicines are not excessive.

Parliament's intention was not lost on the Standing Committee on Industry, which in its review of Bill C-91 in 1997, commented on the potential impact the PMPRB could have on this balance:

"While we would like to think that health policy and pharmaceutical policies are naturally harmonious, such is not the case. The reality is that some policy objectives are in conflict with each other. It is absolutely essential that everyone recognizes that to change one component is to set in motion a new balance, because so many issues are interrelated. Governments must be aware of the

² Price Increases for Patented Medicines: Discussion Paper, March 2005, Appendix 1: Historical Context
<http://www.pmprb-cepmb.gc.ca/CMFiles/notice-Mar05-E15GGG-392005-5938.pdf>

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consequences of these changes in order to minimize disruption and optimize the benefits to both industry and consumers."³

In its 2005-2006 *Reports and Plans and Priorities*⁴, the PMPRB acknowledges the importance of the balance established by Parliament:

"The PMPRB represents the strategic component of the federal government's policy to balance consumer protection and affordable health care with the trade and industrial development objectives of pharmaceutical patent legislation."

In the discussion paper the PMPRB suggests that its mandate needs to be consistent with the objectives put forward by the federal, provincial and territorial committees in their National Pharmaceuticals Strategy. However, it is not the place for the PMPRB to suggest moving to a tighter regulatory environment for drug prices to address underfunding of provincial drug benefit programs. The Board's mandate is established by Parliament and that mandate is to ensure that prices of patented medicines are not excessive, given the factors in the *Patent Act*. It is beyond the scope of the PMPRB's authority to redefine its mandate or to advance pharmaceutical cost containment initiatives either on its own or at the behest of the provinces.

Given the balance contemplated by Parliament, it is Rx&D's position that any review of the PMPRB's guidelines with respect to price increases cannot be conducted in isolation or in the absence of substantial evidence that the process generally is not working. Rather, such policy reforms must be conducted as part of a sectoral review, taking into account not only the PMPRB price review factors, but the entire pharmaceutical policy environment including regulatory approval, intellectual property protection, investment, research & development, health care funding, etc. It is vital that any proposed policy changes seek to maintain the important balance between an affordable, accessible health care system and creating a vibrant investment climate for pharmaceutical research, development and manufacturing.

Consideration of the Three Proposed Regulatory Frameworks

It is Rx&D's view that there is no public policy justification for further limitations on price increases related to patented medicines. Indeed, there should be greater pricing flexibility for patented medicines to ensure pricing is responsive to market conditions, patients have timely access to therapies and that there are sufficient funds available for continued R&D.

Regarding the proposed alternative Frameworks 2 and 3, Rx&D must point out that, clearly, they would increase the regulatory burden on patentees unnecessarily and inhibit the efficiency of the price review process, without offering any benefit to consumers. More importantly, the board has no statutory authority to pursue these initiatives under the Patent Act given that the act limits the ability to impose any requirements for regulatory review before prices are implemented in the marketplace.

³ Fifth Report of the Standing Committee on Industry, *Review of Section 14 of the Patent Act Amendment 1992* (Chapter 2, Statutes of Canada, 1993, April 1997)

⁴ www.tbs-sct.gc.ca/est-pre/20052006/PMPRB-CEPMB/PMPRB-CEPMBBr56_e.asp

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Discussion

Section 85.(1) of the *Patent Act* lists factors that the PMPRB should consider when determining whether the price a medicine is being or has been sold at is excessive. One of the factors is changes in CPI. It is Rx&D's position that PMPRB should only consider a price to be excessive in cases where pricing is excessive based on all factors in the *Act* including the CPI.

The current guidelines for price increases were amended in 1994 following stakeholder consultations that were predisposed to the points of view of provincial drug plans and other non-industry stakeholders. The discussion paper seeks to further erode prices of patented medicines by appealing for stakeholder suggestions for additional restrictions on price increases in isolation – i.e., without taking into account the other factors that influence prices and drug expenditures in Canada or the impact that changing policies would have on industrial development. Indeed, the suggestions in the discussion paper are essentially an opinion survey somewhat akin to asking Canadians if they would like lower taxes.

Some of the suggestions raised in the discussion paper, such as to routinely require that patentees seek approval in advance of price increases, or to require justification of price increases on an other-than-exceptional basis, would remove pricing flexibility, add unnecessarily to the regulatory burden on patentees and would make the price review process even more cumbersome for the PMPRB.

There are frequent references to "price stability" in the discussion paper. From an economics perspective, price stability occurs when prices keep up with inflation. In the case of patented medicines, they have chronically fallen behind the inflation rate. In fact, in real terms (i.e., after taking inflation into account), prices of patented medicines have fallen every year since the PMPRB was established in 1987. Prior to 1993, prices of patented medicines increased nominally each year, but always at levels below the CPI (i.e., they fell in real terms). Since 1993 "nominal" prices of patented medicines have either declined or remained flat. In nominal terms, prices of patented medicines have declined by 6.4% since 1993 according to the figures published by the PMPRB for 2003⁵. Over the same time frame, inflation as measured by CPI has increased by 20.1%⁶. Therefore, in real terms (i.e., after taking into account inflation), prices of patented medicine have actually declined by more than 26% since 1993. Clearly, the prices of patented medicines have not been stable over the past ten years as portrayed by the PMPRB, they have in fact declined significantly.

The fact that prices on average did not increase for several years was the result of patentees responding to market conditions. Over that time period some prices increased, others decreased and many remained unchanged. That more patentees are now considering price increases than in the past, speaks to a change in market conditions and not a move to excessive pricing. There are similar examples in other sectors of the economy. For example, employees may voluntarily forgo salary increases in uncertain market conditions, but would not do so if the result was a permanent regime where salaries could never keep up with inflation.

⁵ PMPRB, *2003 Annual Report*

⁶ Statistics Canada, Change in the annual Consumer Price Index from 1993 to 2003

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Having given due consideration to the three frameworks which represent the spectrum of different hypothetical regulatory systems, the following represents Rx&D's response to five questions pertaining to PMPRB's guidelines.

Rx&D's Response to the Discussion Paper Questions

1. Should the PMPRB's guidelines continue to allow automatic (i.e. without prior approval) price increases?

Rx&D's position is that PMPRB has no authority under the Patent Act to seek prior approval of price increases.

The PMPRB does not have the legal authority to require prior approval of price increases. The *Act* limits the PMPRB's price review powers to the prices at which a medicine "is being" or "has been" sold – it has no authority to review prices at which medicines "will be" sold. The exception is when a patentee voluntarily seeks advisory assistance from Board Staff or a certificate pursuant to sub-section 98 (4) of the *Act*.

Moreover, Rx&D objects to the notion that the current guidelines somehow result in "automatic" price increases of patented medicines. As the PMPRB has noted, price increases over the past decade have been infrequent and well within the limits of the CPI. The evidence clearly shows that patentees have been complying with the existing guidelines.

There is no justification for requiring patentees to seek approval in advance of price increases.

There is also the question of efficiency and smart regulation. As of March 31, 2005, the PMPRB's website indicated that one third of the new medicines introduced in 2004 (as well as several products from prior years) had introductory prices that were still "under review". Moreover, the last PMPRB Annual Report indicated that more than 50 investigations of possible excessive pricing and three hearings were in progress. Given that the PMPRB already reviews the prices (and increases) of all patented medicines twice annually and that the recent prices increases that were the genesis of the discussion paper are, according to the PMPRB's best information, well within the CPI Guideline, what possible purpose would a prior approval price increase guideline serve, other than to possibly increase the workload of the PMPRB staff and add regulatory burden on patentees?

In summary, prior approval would result in additional costs to PMPRB and patentees, and provide no additional benefit for Canadians.

Perhaps most importantly, the PMPRB does not have the legal authority to require prior approval of price increases. The *Patent Act* limits the board's price review powers to the prices at which a medicine "is being" or "has been" sold – it has no authority to review prices at which medicines "will be" sold. The exception is when a patentee voluntarily seeks advisory assistance from board staff or a certificate pursuant to sub-section 98 (4) of the *act*.

Under the *Patented Medicines Regulations, 1994* (the *Regulations*), patentees are required to file their sales and price information within 30 days of the end of each six month reporting period. There is no provision in the *Regulations* that requires patentees to notify the Board of price increases between reporting periods. The PMPRB has recently concluded a separate consultation process on proposed changes to the *Regulations* including an amendment that would require patentees to notify the PMPRB

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of price increases 120 days in advance of their implementation. The PMPRB has no authority to regulate prices before they have been implemented, as the *Patent Act* refers only to the price at which a medicine is being or has been sold, not to the price at which it will be sold in the future.

In addition to the legal questions, the notification to PMPRB of proposed prices and the suggestion that price increases could be reviewed in advance is troubling for the following reasons:

- It raises competitive issues – price changes are highly confidential and time sensitive - how will PMPRB keep them confidential?
- Wholesalers and distributors may stockpile and participate in arbitrage once price increases become known
- The PMPRB's current methodology is to monitor average selling prices to determine compliance. Is the PMPRB now proposing to use list prices as the main determinant of compliance?
- Patentees take pricing decisions very seriously. They take into account many factors, some of which are variable and unpredictable. For these and other reasons pricing decisions are implemented very soon after they are made taking into consideration most current information. What if a patentee changes its mind?
- It would add to the already significant regulatory burden on patentees, and create inefficiencies to the price review process.
- Would prior approval delay submission of patented medicines to provincial formularies?

2. Are there considerations other than, or in addition to, the CPI that should be used to review price increases?

Price increases up to CPI are by definition not excessive - price increases beyond CPI may only be considered excessive after consideration of all factors listed in the Act.

Section 85.(1) of the *Patent Act* lists factors that the PMPRB should consider when determining whether the price a medicine is being or has been sold is excessive. Changes in CPI is one factor, not the factor that PMPRB must take into consideration. The PMPRB does not have the authority to disregard factors provided in the *Patent Act* including changes in CPI when considering if prices are excessive. A change to the guidelines to further limit the use of CPI as a basis for determining if price increases are excessive is inconsistent with the provisions of the *Patent Act*.

Moreover, it should be noted that a price that exceeds the increase in CPI is not in and of itself, excessive. For example the price of a medicine that has increased by more than CPI should not be considered excessive if its price remains within the range of prices in its therapeutic class or the range of international prices.

The CPI guidelines were amended in January 1994 to address PMPRB concerns that a patentee could accumulate allowable price increases and implement a large increase in a single year. The PMPRB had proposed an amendment to limit price increases to a one year increase in the CPI, however this created new concerns about the loss of

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pricing flexibility and the complicated process that companies would have to follow to determine allowable prices. The resulting Guideline was ultimately more complicated than initially anticipated. Under its terms, price increases are limited to the cumulative change in the CPI over three years, and any price increase in a given year cannot exceed 1.5 times the forecast change in the actual CPI.

In summary, the 3-year methodology has not provided the pricing flexibility that was intended by the Board. Accordingly, the PMPRB should return to the original CPI methodology that was in place between 1988 and 1993.

In addition, Section 7.1 of the guidelines specifies that at no time may Canadian prices of new or existing patented medicines exceed the range of international prices in comparator countries.

In the discussion paper, the PMPRB says that European countries are taking steps to limit or even reverse pharmaceutical price increases, and that Canada should be prepared to take a similar approach in order to keep Canadian prices in line with the median international prices. However, it is important to note that, unlike Canada, some of these countries allow free pricing of new patented drugs and all allow free pricing of drugs that are not reimbursed under public health insurance plans. In Germany and the United Kingdom, new active substances are priced freely and most innovative new medicines are reimbursed upon receiving marketing approval. Also, cost containment measures are balanced with policies to encourage pharmaceutical research and development and access to new medicines. Recent price cuts in the United Kingdom were arrived at through the negotiation of an agreement between government and industry⁷. In France and Germany, premium pricing for patented drugs may be offset by rebates paid by manufacturers to government health plans.

While Rx&D recognizes that patented medicines are one of the most stringently regulated products in the Canadian market, it is particularly important to ensure that any guidelines maintain (and ultimately improve) pricing flexibility in Canada. Given the complex interaction of regulations and policies (both domestic and international) concerning the research-based pharmaceutical industry, it is essential that any policy changes be contemplated in as large a context as possible to notably ensure that Canada's regulatory and investment environments remain efficient and competitive.

3. How often should price increases occur? (e.g. every year, once every 3- 5 years, only after a certain introductory period, when justified)

Rx&D's can identify no public policy need for the PMPRB to set limits on the timing of price increases. To do so, or to require justification of price increases in advance, would exceed the PMPRB's statutory authority.

The PMPRB has provided no evidence to indicate that patentees have been taking frequent price increases, or that Canadian prices are excessive compared to other countries. The PMPRB has claimed often that the existing guidelines, in tandem with provincial formularies, have been successful in controlling price increases and that

⁷ Summary of the Pharmaceutical Price Regulation Scheme 2005:
www.dh.gov.uk/assetRoot/04/09/33/93/04093393.pdf.

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prices have been stable for the past decade. Indeed, preliminary analysis of top selling patented medicines suggests that price increases have been increasing at an average annual rate of less than 1% annually between 2002 and 2005 (as of April). Moreover, the PMPRB reports that Canadian prices on average have remained at levels five to 12% below the international median from 1994 to 2003.

There are no provisions in the *Patent Act* with respect to the timing or frequency of price increases. The Board's statutory powers are limited to determining whether the price of a particular patented medicine is excessive. If a particular price increase is consistent with the factors under the Act, it should not matter if it is taken all at once or in several increments or at what time of year the increases are taken. Given that the *Act* is silent on both timing and frequency of price increases, the Board has no authority to impose limitations that go beyond the specific factors listed in section 85 of the *Act*.

4. If justification is required, what criteria should be considered?

Rx&D's position is that justification of price increases should only be required after the fact (i.e., not in advance) and only in cases where, for example, the price increase exceeded the CPI, Therapeutic Class and International Price Guidelines by a significant margin

The *Act* already lists in section 85 the factors that the Board must consider in determining whether the price of a patented medicine may be excessive. In Rx&D's view, these factors should be considered in the broadest sense and not in the restrictive manner in which they are currently applied. For the price of a patented medicine to be truly excessive, it must exceed more than one of the factors listed in section 85.

Moreover, the PMPRB has well-established policies and procedures (e.g., criteria for commencing an investigation) for enforcing its guidelines in cases where prices may appear to be excessive. There is no need to over-regulate and establish yet another set of policies and procedures for price increases that the PMPRB has already acknowledged are within its current guidelines.

5. Given that the CPI is established in the Patent Act as a factor to be considered by the PMPRB, do you have any comments on its appropriate application in future guidelines?

Rx&D's believes that patentees' introductory prices should be compared with CPI-adjusted prices of comparator medicines when conducting a therapeutic class comparison test

Relying on the prices of existing medicines within a given therapeutic category (treatments that have not been increased in price within the past 10 years and which reflect a time when R&D costs were much lower than today) as comparators to estimate the price of new medications is not reasonable.

CONCLUSION

In order to achieve the full potential of Canadians' massive investment in health care, appropriate use of innovative prescription medicines and other innovative technologies is essential. As experts have pointed out, the appropriate and timely adoption of innovation in health care is critical in order to deliver the needed productivity gains in the health care sector. Conversely, a cost-centric approach to managing innovation in health care will diminish patient outcomes and unnecessarily increase overall costs.

The PMPRB has acknowledged that the "control of one factor (e.g., drug prices at the factory or retail level) does not guarantee control of total expenditures. Even if prices were constant (or declined, as have patented drug prices on the whole), changes in other factors (e.g., volumes of drug products consumed) could easily produce large increases in total drug expenditures."⁸

This statement, while true, highlights a serious challenge faced by the PMPRB. As a quasi-judicial agency, the PMPRB should restrict its activities to reviewing individual cases where there is clear evidence of excessive pricing. It cannot seek to become a policy setting administrative body without compromising its independence as a quasi-judicial board.

The PMPRB suggests that tighter guidelines for price increases would be consistent with the objectives put forward by the federal, provincial and territorial governments' in their National Pharmaceuticals Strategy. However, it is not the place for the PMPRB to suggest moving to a tighter regulatory environment. It is beyond the scope of the PMPRB's mandate to advance pharmaceutical cost containment initiatives either on its own or at the behest of the provinces.

Finally, given the overriding purpose of the *Patent Act* and the Government of Canada's recently announced smart regulation objectives of improved regulatory governance, as well as better cooperation and coordination among federal departments and with other levels of government, Rx&D strongly believes that any suggested changes to important elements of price control should be contemplated only in the context of a formal review of the *Patent Act* and with due consideration for relevant health, industrial and pharmaceutical policies in Canada.

⁸ PMPRB, *Annual Report 2003*, p. 25.