FEDERAL HEALTH PARTNERSHIP

August 25, 2006

**To:** Dr. Brien G. Benoit

**Re:** Patented Medicine Prices Review Board Request for a Written Comments in Response to May 2006 Discussion Guide for the Consultation on the Board's Excessive Price Guidelines

## Introductory General Remarks

Thank you for the opportunity to comment on PMPRB's Excessive Price Guidelines. The issues surrounding pricing in the pharmaceutical industry are complex and evolving and the need to continuously respond to a changing environment present both challenges and opportunities. The May 2006 Discussion Guide for the Consultation on the Board's Excessive Guidelines is an excellent document with very useful and pertinent information that will serve as an invaluable tool in ensuring that PMPRB's guidelines continue to be relevant in today's pharmaceutical environment.

## Response to Specific Questions

***Issue 1: Is the current approach to the categorization of new patented medicines appropriate?***
*(Q1,Q2, Q3: Are the new patented drug categories and their definitions appropriate? Is it important to distinguish a medicine that offers "moderate therapeutic improvement" from a medicine that provides "little or no therapeutic improvement?" If yes, why is it important? If not, why not?)*

The current Excessive Price Guidelines use three separate categorizations in determining the appropriate price test used by PMPRB staff in deciding whether a manufacturers' ex-factory gate price is non-excessive. In order to address the issue of whether the current approach is appropriate or not it is important to understand the context within which the current approach evolved to better guide how to proceed in the future. An understanding of the issues that were considered by the PMPRB in developing the current categorization of new patented medicines would provide a useful foundation for assessing appropriateness and framing future discussion.

*Historical Context*

PMPRB's jurisdiction and mandate is derived from provisions in the *Patent Act*. The *Act* itself provides for a fine balance between industrial policy on the one hand, and consumer/patient protection on the other. The patent protection extended to the pharmaceutical industry with Bill C-22 and C-91 was largely intended to strengthen the incentive to conduct innovative R&D in Canada, however, the extended patent protection was done within the context of governments desire to protect consumers and, by extension, Canada's publicly funded health care system. The need to ensure that the regulatory price regime ensures that prices for Canadians are not excessive was

strengthened in 1993 when Bill C-91 gave the PMPRB increased remedial powers and shifted ministerial responsibility for the PMPRB to the Minister of Health from the Minister of Consumer and Corporate Affairs (now the Minister of Industry). In essence, the extended patent protection is on one side of the industrial policy equation, and consumer protection and hence PMPRB's core mandate is on the other.

In previous consultations conducted by the PMPRB, some stakeholders have argued that the greater the innovation (i.e. breakthrough vs. moderate or no improvement to existing therapy) the greater should be the financial reward/price premium for new patented medicines. The current PMPRB pricing guidelines were not intended to be used as a vehicle for encouraging and/or rewarding certain kinds/levels of innovation. Although PMPRB is a federal independent quasi-judicial body operating at an arm's length from the Minister of Health, it is part of the Health Portfolio with a regulatory mandate "to protect consumers and contribute to Canadian health care by ensuring that prices charged in Canada by manufacturers for patented medicines are not excessive." The extended years of exclusivity is the policy lever used to provide the governments R&D objective; the role of the PMPRB is strictly focused on consumer protection.

*Factors in the Patent Act*

The *Patent Act* identifies the factors to be considered in assessing a price, however, the approach of setting categories as part of the price review process is based on an administrative/operational decision. The *Patent Act* itself does not provide a clear direction behind the approach of categorizing drugs based on scientific novelty and therapeutic advancement. The appropriateness of the current approach should be examined within the historical context within which the price regulation scheme and guidelines were developed as well as PMPRB's administrative and operational feasibility in incorporating the factors listed in the legislation as part of the price review process.

The primary factors listed in the legislation identify the need to consider the price of other medicines in the "same therapeutic class" nationally and internationally. The extent to which these factors may be considered and the availability of scientific information is impacted by the type of drug in question. For example, it may not be feasible in the case of "breakthrough" drugs to consider a therapeutic market, therefore an international price comparison in these cases may be of greater significance and perhaps the need to consider other factors (secondary) may also play a greater role in determining whether a price is non-excessive. In the case of drugs that offer "little or no therapeutic improvement" over already available therapies a therapeutic class comparison is a lot more appropriate and feasible. The legislation identifies the factors that should be considered in the price review, it does not identify the how and hence there is considerable flexibility on the part of PMPRB in developing the excessive price guidelines.

*Consumer Protection*

Since PMPRB's mandate is one of consumer protection, the current guidelines and any changes need to be considered within that perspective. From a consumer protection standpoint, the approach of categorizing drugs can serve two distinct functions. Firstly, price can serve as a signal to consumers about the relative therapeutic merit of a drug (this information could play an important role in controlling market power abuse). Given the nature of the pharmaceutical market, the approach to categorize drugs based on the level of therapeutic improvement is valid, particularly if the categorization provides consumers and physicians with the ability to make more informed decisions around therapeutic choice and to ensure drugs that do not offer a therapeutic advancement over existing therapies do not increase the average cost of treatment. The introduction of new medicines that increase the cost of therapy without providing therapeutic improvement over existing treatments is a significant issue for both consumers and Canada's publicly funded drug plans. A categorization and pricing scheme that addresses this issue would have a significant impact on protecting both consumers and contributing to Canadian health care.

Secondly, the level of consumer protection needed and/or warranted may depend on the number of therapeutic/treatment alternatives already available on the market. For example, in the case of a drug that provides little or no therapeutic improvement over existing therapies, the market may be relatively effective in ensuring a non-excessive price, however, in the case of moderate improvements or breakthrough drugs, the likelihood of market power is greater and so is the need to protect consumers. The approach of categorizing drugs from both a provision of information perspective and assessment of potential market power[1] perspective provides a solid foundation to protect consumers and assessing the way in which the factors listed in the legislation should be considered.

It may also be appropriate and more feasible to provide a categorization and/or pricing premium to new drugs after a sufficient time on the Canadian market; and once there is solid therapeutic effectiveness evidence and the drug's relative contribution can be assessed with greater certainty. This is particularly relevant to be able to distinguish between the drugs that offer little improvement over existing therapies and drugs that have a modest improvement. The recent concerns raised by public plans around expanded indications and PMPRB's pricing guidelines also provide some justification for post marketing/ retrospective categorization and price reviews.

In summary, it may be valuable for PMPRB to provide more background on how the current approach to categorize drugs was developed. There may be a common perception that the rationale behind categorizing drugs is based on providing a reward to industry for greater therapeutic value and innovation, however, PMPRB's regulatory mandate is clear: "to protect consumers and contribute to Canadian health care by ensuring that prices charged in Canada by manufacturers for patented medicines are not excessive."

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[1] The Competition Bureau's "Enforcement Guidelines on the Abuse of Dominance Provisions". Section 78 and 79 of the Competition Act may provide some useful reference points.

Hence it is important to interpreting the categorization of new patented medicines within the context of consumer protection and contributing to Canada's health care system.

***Issue 2: Is the current approach used to review the introductory prices of new patented medicines appropriate?***

In setting the maximum non-excessive price the PMPRB guidelines set out two broad price tests, a therapeutic class comparison (TCC) and an international price comparison (IPC). Of particular interest is the price test used by the PMPRB for drugs that are categorized as offering moderate, little or no therapeutic advantage over comparable medicines (category 3) and the relative relationship of that price test to the one used for drugs categorized as breakthrough drugs (category 2). That is, for category 3 drugs a price above the median IPC is not considered excessive, whereas a price above the median IPC would be considered excessive for category 2 drugs; this apparent difference in defining an excessive threshold does not seem appropriate.

Based on the information provided in the consultation document, it is clear that in a significant percentage of cases (65% in 2003 and 2004) the TCC test allows for a higher price than a median IPC test. It's also evident that in the majority of cases, the TCC test currently is the one that sets the maximum non-excessive (MNE) introductory price for the majority of category 3 drugs and in a significant percentage of cases this MNE is higher than would be considered appropriate for breakthrough drugs. It is not clear why a higher price ceiling is permitted for category 3 drugs than category 2 drugs. For example in 2004, 65% of category 3 drugs were allowed to price above the median IPC and 25% actually did price above the median IPC, a price that would have exceeded the maximum had that drug been deemed to offer a significant therapeutic improvement over existing therapies.

Given that most drugs are priced below the maximum non-excessive price ceiling set by PMPRB's guidelines, it would seem appropriate to have a more consistent international price comparison for both category 2 and 3 drugs.

*Question 1 & 2:*
*Are the price tests currently used to review the prices of new medicines in the various categories appropriate for that category? Why? Why not? If not, how could these tests be amended to improve their appropriateness?*

*If you think that medicines that offer "moderate therapeutic improvement" should be distinguished from medicines that provide "little or no therapeutic improvement" what would the appropriate new price test be?*

Since the median international price test (MIPT) sets the maximum ceiling for breakthrough drugs (category 2), PMPRB should consider having the MIPT set the MNE for category 3 drugs as a second test after the TCC.

The legislation governing PMPRB's mandate defines the primary and secondary factors that must be considered in assessing whether a price in any market in Canada is

excessive. National and international prices of medicines in the same therapeutic class are identified as primary factors in assessing the price of a patented drug. How these prices are considered is left to the discretion of the Board and provides for significant flexibility. For instance, at the present time, the prices and cost of therapy internationally are not taken into consideration; it would be appropriate to do so.

With respect to the prices at which other medicines in the same therapeutic class have been sold in the relevant Canadian market, the current approach of using the highest price is a significant cost driver for public drug plans and does not provide the right signal to consumers regarding the relative therapeutic merit of the new drug. Given the complexity in relative assessment of optimal therapeutic choice for both patients/consumers and physicians, and given the market imperfections that are inherent in the pharmaceutical market, a price more reflective of the relative merit of a new drug would be very appropriate. It may be more fitting to use the average cost of existing therapy, or the price of the drug that is the "gold standard" of therapy, i.e. the most efficacious, effective and cost effective as the ceiling TCC price as long as that price does not exceed the MIPT.

The PMPRB was created to protect consumers by ensuring that manufacturers do not abuse the increased patented protection granted to them by Bill C-22 and C-91. Although generally speaking, the potential to create and exploit monopoly power may diminish as the number of therapeutic comparison increases, the difficulty within the pharmaceutical market is that consumers and physicians are not fully able to assess the relative merit of a new therapy due to the expert knowledge required to do so as well as the lack of available evidence (e.g. head to head trials). Other relevant factors that provide for increased market power by the patentee is the pharmaceutical market dynamics; a) the physician does not always take price/cost into consideration when making prescribing decisions and may be significantly influenced by detailing efforts of the pharmaceutical industry and b) patients do not always pay for the therapy prescribed to them due to public drug plans.

Therefore, the PMPRB, in its consumer protection role, can categorize and differentiate new drugs based on therapeutic merit and then use the prescribed factors in the legislation to assess whether a price is excessive based on a differential application of these factors. For example, if there is no compelling evidence that a new drug provides a therapeutic improvement over existing therapies, a price could be defined as excessive if it is greater than the most cost-effective therapy already on the market or perhaps a median or mean therapeutic price could define the ceiling. If at a later date the drug proves to provide a moderate improvement, then some price premium may be allowed, perhaps a price increase that is 2 times the CPI (rather than 1.5 as is the case today). Also, since the social value of new drugs decreases with the number of available therapeutic alternatives, a drug that proves to have little or no therapeutic advantage over time and is within a well populated therapeutic market (an example may be a therapeutic market with more than 4 available therapeutic alternatives[2]) may be subject to a price decrease, perhaps 1.5 or 2 times the CPI.

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[2] There are lots of markets for which a large number of alternatives exist, NSAID's; H2 Antagonists, Statins; ACE inhibitors, Calcium Channel Blockers, etc. F/P/T and PMPRB studies have demonstrated that

PMPRB should consider maintaining the current practice of limiting all prices to the lesser of the relevant therapeutic comparison or the relevant international price comparison. (PMPRB should also consider reviewing the rationale and possible impact for using median rather than mean.)

When a new drug is introduced into the market place, the evidence of its effectiveness and therapeutic role is often limited, hence there is a strong argument to expand PMPRB's current process to include a reassessment and readjustment after a designated period of time. A reassessment of the price based on increased evidence is appropriate within the current legislative and regulatory framework and would be consistent with what the PMPRB currently does in reassessing a price if there are not a sufficient number of countries included in the initial international comparison. A reassessment would also provide for an opportunity to do a more appropriate international test as the number of countries included in the original assessment may not fully capture an international price level since at the time of introduction into Canada, other countries may not have had the drug introduced.

The data presented in the Discussion Guide document provide some evidence that in the majority of cases, PMPRB's current guidelines do not impose a constraint on the price charged by manufacturers (for example, in Figure 6, p. 12, only 18% of prices for category 3 drugs are equal to the maximum TCC). This evidence could mean that the market forces that exist in Canada are sufficient in controlling monopoly power of the patentees in the majority of cases, or it could mean that the impact of price regulations could be strengthened and PMPRB could play a greater role in protecting consumers and contributing to the sustainability of Canada's health care system.

*Question 3:*

*For price review purposes, "comparable medicines" are medicines that are clinically equivalent". Do you have any suggestions as to principles or criteria that should be used in determining how to identify "comparable medicines" for the purpose of inclusion in the above price tests?*

As discussed above, the lack of evidence early on in a product's lifecycle suggests that initially, a fairly restrictive definition of "comparable medicines" should be considered. The current approach used by the PMPRB is appropriate, however, PMPRB should consider augmenting the current approach with utilization data analysis so that drugs that may have the same indication or therapeutic use as the new medicine under review are only included if they represent a significant enough market or play a moderate to substantial role in therapy. Inclusion of obscure drugs that are only used marginally may

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a significant cost issue for consumers and public plans is the practice of introducing "me-too" drugs that increase the average cost of therapy without providing an improvement over existing therapies. Patentees can enter established therapeutic markets and through significant detailing efforts both expand the market, switch patients to their new drugs, for which there is no generic competition, and most importantly influence physician prescribing for newly diagnosed patients.

need to be included with greater caution as a comparable medicine even if they are part of the same ATC sub-class and have the same primary indication. One option may be to look at market share as an indication of whether a drug has a significant enough role in therapy and should thus be considered in the review.

*Question 4*

*Under the current Guidelines, Board Staff compares the Canadian average transaction price of the new medicine to the prices of the same medicine sold in the seven counties listed in the regulations. However, Section 85(1) of the Patent Act states that the Board should take into consideration "the prices of other comparable medicines in other counties". Should the Guidelines address this factor?*

*If so, how could this factor be incorporated into the price tests for new medicines?*

The international prices of other medicines in the same therapeutic class is listed in the same paragraph as the international price of the medicine itself and hence is clearly intended as a primary factor that should be considered in determining whether a medicine is priced excessively. The objective of including an international therapeutic class assessment may be grounded in the need to ensure that the IPC test for the new medicine is appropriate to make. For instance, if a new drug is likely to be used as an agent of last resort in a specific country because of specific clinical guidelines that exist within that country or for whatever other reason, then the implications of a high price in that country may be marginal to that country but significant for Canadians.
The policy objective however, of including this factor for consideration must be made clear before the how is considered.

**Issue 3**
**Should the Board's Guidelines address the direction in the Patent Act to consider "any market'?**

*Question 1*
*Given the price variations by provinces/territories and classes of customer illustrated in the previous figures, is it appropriate for the Board to only consider the ATP calculated based on the total revenues from the sales for all provinces/territories and all classes of customer? Why? Why not?*

*Question 2*
*If the current ATP calculation is not appropriate, should the Board review the prices to the different classes of customers and/or the different provinces and territories for all DINs? Or should this level of review be done on a case-by-base basis, where there is a significant variation in the prices charged?*

The current price review process is based on the calculation of a single average transaction price (ATP) for all of Canada across all customer classes. As a result, some customers may be paying prices that would be considered excessive but are permitted due to the averaging process. It does not seem appropriate that any customer should pay a price above the maximum non-excessive price. The Board should consider reviewing the prices to the different classes of customers and/or provinces and territories for all DINs. The Board already has the data and the technical expertise to ensure that no customer is paying an excessive price. There may be some issues around retroactivity, however, for all new drugs, PMPRB should consider calculating the ATP in a way that ensure that manufacturers do not price above the MNE to any customer in any jurisdiction.