April 27, 2009

Dr. Brien G. Benoit
Chairperson, Patented Medicine Prices Review Board (PMPRB)
Box L40, Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario K1P 1C1

Dear Dr. Benoit:

On behalf of *Canada's Research-Based Pharmaceutical Companies* (Rx&D), I would like to thank you for the efforts the PMPRB has made to increase the dialogue between our respective organizations. The recent series of meetings with representatives from our respective Boards was helpful to understand the PMPRB's views and to illustrate our issues that are of importance to the innovative bio-pharmaceutical industry. While we still have issues of concern, such consultations have helped us prepare our constructive comments regarding the recent Notice and Comment package on the Draft Revised Excessive Price Guidelines released on March 25, 2009.

The bilateral meetings have set a tone that recognizes the value of discussion and has allowed for a better mutual understanding of each other's issues. Rx&D would encourage the PMPRB to ensure the continuation of such a productive policy.

Regarding the technical aspects of the new guidelines, Rx&D has provided comments and suggestions in the Appendix attached to this letter. However, there are three main points that Rx&D would like to raise.

1. The Therapeutic Class Comparison Test (TCC) and the Reasonable Relationship Test (RRT) as defined in the Draft Revised Excessive Price Guidelines still requires clarification. The TCC and RRT provides an inadequate measure of certainty for patentees attempting to establish their prices while the application appears inconsistent and illogical.

2. How the Any Market Price Reviews will be undertaken and the criteria for launching such a review appears to be inconsistent with our recent discussions and vague for existing drugs. This raises even greater concern as it impacts the ongoing monitoring by patentees to ensure compliance with the guidelines.

3. The proposed timing of the implementation of these guidelines is problematic. As with prior changes to the guidelines, a mid year implementation date of any changes will lead to inconsistencies and unnecessary confusion for both industry and Board staff. In addition, the outstanding resolution of the judicial review in the summer of 2009 could have further implications for these guidelines.

.../2

We recognize the PMPRB has conducted a lengthy exercise spanning approximately three years and that there is a desire from both the PMPRB and stakeholders to conclude this work. However, solutions being offered must be carefully considered and not sacrificed due to a desire to expedite a conclusion to this work. If the opportunity is missed, both the PMPRB and its stakeholders may have to live with a system that will end up being more imperfect than the one it was meant to improve upon.

Sincerely,

Russell Williams,
President

c.c. Sylvie Dupont, Secretary, PMPRB

Appendix: Rx&D Technical Submission to PMPRB

This submission identifies many of the concerns Rx&D has with the PMPRB's Notice and Comment package on the Draft Revised Excessive Price Guidelines released on March 25, 2009. It should be noted that the issues raised in this document do not necessarily reflect all of the concerns of our members.

Legal Framework

Origin, Mandate and Structure and Operation of the PMPRB

Rx&D acknowledges the PMPRB was established in 1987 under amendments to the *Patent Act* (Act) made under Bill C-22. With respect to "consumer protection", the PMPRB was established in part to perform a limited oversight function with respect to the potential for excessive pricing of patented medicines – price review rather than price setting. Rx&D believes that overly expansive interpretations of the PMPRB's original mandate lie at the heart of many of the issues that have arisen between Rx&D and its members and the PMPRB in recent years. Rx&D therefore believes it is important for all stakeholders to clearly understand the history, spirit and context of the PMPRB's statutory mandate. The purpose of the PMPRB is to guard against excessive pricing and to report on sales and R&D expenditures.

The proposed mandate in the draft guidelines fails to provide the context for the powers of the Board. If the mandate of the Board is to mention one of the purported "pillars" of the changes to the Act proposed in 1993, then it should at least provide the full context of those changes. The impetus for the subsequent change, in 1993, to the Canadian patent regime was the need for Canada to comply with its international trade obligations.

Following the 1987 amendments to the Act, the international dialogue on trade issues continued in the context of the Uruguay Round of the General Agreement on Tariffs and Trade, the precursor to the World Trade Organization (WTO). The WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement provided for minimum standards of patent and other intellectual property rules. The WTO TRIPS obligations placed limitations on Canada and other member countries with respect to compulsory licensing (Article 31), and also formalized the rules on what kinds of patents member states were required to recognize (Article 27).

On both issues, the Act as amended in 1987 did not conform to these minimum standards. At around the same time, the North American Free Trade Agreement was signed which contained provisions that were largely similar to those in TRIPS but with earlier deadlines for change implementation. Bill C-91, amending the Act in 1993, was introduced to ensure that Canada would conform to its international obligations, by putting in place a scheme that promoted innovation while ensuring that drugs are not excessively priced. There was never any suggestion that there would not be price increases as a result of the new scheme.

With respect to the PMPRB's mandate, it was repeatedly emphasized during the legislative process on Bill C-22 that the Board was not being created as either a price-setting or a profit-control body, in part because of constitutional limitations. The then Minister of Consumer and Corporate Affairs, Mr. Harvie Andre stated, in committee proceedings: "The drug prices review board is not in the profit-setting business. It is in the business of keeping prices in control."

Rx&D also wishes to emphasize that the guidelines are non-binding in nature. The legal framework under which both the Board and Board staff operate is set out in the Act. The Guidelines are merely administrative instruments created by the PMPRB itself. They should therefore not deviate from the mandate and jurisdiction of the administrative tribunal, which is set out in the Act. Finally, it should be noted that the Act contains no reference to consumer interests as being related to the mandate of the PMPRB.

Publication of Patentee Information

We agree the PMPRB has the right to publish pricing information which is publicly available. On page i. of the document it is stated that the PMPRB will release all pricing information reported on Form 2, Block 5 without the patentee's consent and this information is by definition required to be publicly available.

However, this information, or part thereof, is still privileged pricing information as some companies provide pricing data that may not be in the public domain due to various market conditions such as hospital prices in some markets. Furthermore, the release of Form 2, Block 5 information would contradict the PMPRB's rationale provided on page iii for not being able to publish the CPI-Inflated Maximum Average Potential Price. As stated, the confidentiality provisions of the Act protect commercial prices filed by patentees.

Furthermore, it is not clear why the PMPRB has abandoned, in these Draft Revised Excessive Price Guidelines, the following principle that is in the current guidelines: "*Accordingly, the governing principle is that of confidentiality.*" (Section 4.2 of the PMPRB's Compendium of Guidelines, Policies and Procedures).

The PMPRB must protect commercially sensitive information as stated in the Act. Why then would the PMPRB feel compelled to release information that is not always in the public domain? The rationale has not been provided in the document. The current system of seeking patentee consent is appropriate and legally correct.

New Terminology

Rx&D is supportive of providing greater clarity around the terminology employed by the Board. The modification of the Maximum Non-Excessive Price to the Maximum Average Potential Price and the Non-Excessive Average Price is an attempt. However, how they will be used for the purposes of the various pricing tests still requires clarification prior to the implementation of the proposed guidelines.

Levels of Therapeutic Improvement

It should be clarified as to why the PMPRB felt that secondary factors do not carry sufficient weight to move the level of therapeutic improvement from moderate to substantial improvement when a multi-stakeholder working group (the Working Group on Therapeutic Improvement) organized by the PMPRB recommended the exact opposite.

Introductory Price Tests

General Comments

The PMPRB's proposal that the Therapeutic Class Comparison Test (TCC) and the Reasonable Relationship Test (RRT) will be based on the new National Non-Excessive Average Price (NEAP) would penalize manufacturers for entering into benefit agreements with stakeholders by forcing the allowable introductory price for new drugs and line extensions to the price of existing products that offer benefits. The impact of this proposed pricing policy would serve to discourage manufacturers from offering benefits to stakeholders.

Reasonable Relationship Test

By restricting the RRT application to those instances whereby the products have the same chemical entity and same indication and use would introduce a great deal of uncertainty for patentees. One example would be the introduction of a lower strength that is targeted towards a specific patient population that will benefit from a lower strength, in this case the indication difference would potentially preclude the application of the RRT based on the proposed criteria. Therefore, we recommend that this provision be removed.

Therapeutic Class Comparison Test

According to the new guidelines, the TCC will be based on using the new NEAP. However, the NEAP is derived from the National Average Transaction Price (ATP) which might include various benefits related to a product. Given this fact, it is not clear as to the rationale or the necessity as to why a new product must be limited and compared to a price to those existing products that offer benefits.

Patentees require fairness, predictability and transparency of comparator prices for planning and pricing strategy decisions. The proposed methodology does not offer a predictable comparator price that protects confidentiality and treats all patentees fairly and consistently.

For example it is not clear as to what public price would be used that is "sufficiently close to the NEAP"? Using a patentee's own ATP in the TCC as well as for lines extensions and combinations products would unduly punish a patentee for offering benefits. It provides a double standard in that a competitor could use the patentee's list price in a similar situation. The timing of the launch could also produce two different introductory prices.

The other issue with the PMPRB stating that a price is "sufficiently close to the NEAP" is that it does not adequately protect pricing confidentiality. Without realizing it, the use of this terminology could be construed that the PMPRB is also signalling to a patentee that a competitor's list price of a comparator drug product is not "sufficiently close" to the NEAP.

Using "sufficiently close to the NEAP" can cause an additional issue. If a patentee uses the public list price to price its own product that it believes conforms to the PMPRB guidelines, the Board could still determine that this publicly available list price was not an appropriate comparator and force the patentee to lower the price of its product. If such an instance were to occur, the perception would be that the patentee intentionally tried to sell its product at an excessive price when this was clearly not the intent, but due to the lack of clarity and predictability of the guidelines.

Rx&D recommends the PMPRB use: a National or the highest Market-Specific NEAP that is free from benefits; or the pre-contract price (i.e. DIP methodology); or a published price list; or the new Maximum Average Potential Price. Such suggestions would provide greater clarity to patentees and the Board Staff; it is consistent with the excessive price standard of the Act; and it is consistent with the recent decision of the Board in the *Adderall XR* case.

International Therapeutic Class Comparison Test

The main concern regarding the International Therapeutic Class Comparison Test (ITCC) is that while the PMPRB has modified its position on the inclusion of generics in the ITCC test, Rx&D still reiterates its concern (which is supported by the recommendation of multi-stakeholder Working Group on International Therapeutic Class Comparison) that all generics should be excluded. The PMPRB must provide a rationale as to why this is necessary. Industry is of the view that any generic comparison will significantly skew the results of the test.

Superior/Inferior Wording

Price tests for slight to no improvement products without direct comparators, will now be based on the prices of "superior" products and the price test will look at the price of lowest priced "superior" product (potentially including generics depending on the class of drugs), this is not reasonable given you have not defined what you mean by "superior". Additionally the proposed associated price test could possibly create a price benchmark based on a generic version of a product, which may not allow for the commercialization of the new product entry.

The language used in the document of a superior or inferior product is disconcerting given such a decision is outside the scope of the PMPRB. For comparisons purposes, it is reasonable to determine which products are comparable and how they fit into the current therapeutic categories, but no where in the Act does it state the PMPRB should determine which products are superior and inferior.

Therefore, Rx&D recommends the PMPRB completely remove Part III: Chapter 2: Section 2.9 (and related Section 2 from Schedule 8) from the draft guidelines. Should no comparator be found for that category, Section 2.10 in the new guidelines would be the test (or section 8 in Schedule 8). This is the practice as stipulated in the current guidelines and there is no compelling reason to depart from this approach.

Any Market Price Reviews

The proposed Any Market Price Reviews is problematic. It is recognized that the PMPRB has made an attempt to clarify the language and the rationale behind this proposal. Unfortunately, there are still several outstanding issues.

The evidence provided to justify such a proposal does not seem to support the Board's desire to undertake any market price reviews. The proposed any market price reviews is not aligned with the intended benefits of creating greater certainty, simplicity and transparency for all stakeholders. The recent consultation package reported that evidence for the need for such a proposal was provided in the Board's Discussion Guide of May 2006. The following quote from that discussion guide states the following:

> "*...that in the majority of cases* (emphasis added) *(i.e., between 74% and 89% of cases) the prices charged at the provincial or territorial level are in the range of plus or minus 5% of the MNE price. In a small percentage of cases,* (emphasis added) *prices in the provinces and territories are as much as 25% above the MNE price. Conversely, in a small percentage of cases, prices in the provinces and territories are as much as 25% below the MNE price* (emphasis added)."

Given the nature of the evidence provided, it is not clear why the PMPRB would want to significantly increase the regulatory burden and increase the reporting complexity for patentees given the majority of cases are in the same range.

While the actual reporting requirements and format do not change, patentees will have to move from monitoring one national ATP and MNE to 17 NEAPs. Patentees will be required to track and extract contract specific fluctuations across all markets related to contract expirations.

Given the requirements outlined for the DIP methodology, patentees will likely have to amend their contracting approach and require contracting partners to provide more detailed information, thereby increasing the workload and regulatory burden. We are not sure if the PMPRB has a full appreciation of the number, level and scope of the contracts in place across Canada, and has not fully assessed the impact on patentees but also on the broader set of stakeholders.

Other issues with the proposal require clarification:

1. Not clear or defined as to the criteria which will be used to determine how the PMPRB views the appearance of a national excessive price.

2. Not clear as to what defines a complaint – how transparent will this process be – for instance will the patentee be informed of the scope and nature of the complaint?

3. Not clear nor is it adequately explained how excessive revenues would be calculated if there is a problem.

4. It appears from the way the proposal is worded that, at one point in time, the PMPRB could rule a price non-excessive but at a later date change its opinion and then demand the payments of excessive revenues dating back to the original ruling.

5. The PMPRB has not provided any examples or explained how all of the various provincial/territorial ATP's will impact within an individual customer class. For example, the hospital class could have tender versus non-tender pricing. It is not clear then how a patentee can expect to manage all of the ATP's across all the class and market levels.

Rx&D would like to reiterate its long standing concern that to apply any market price reviews on a broad basis, will create a continuing downward pressure on prices. Because of the unpredictability and lack of clarity, patentees will be pushed to maintain prices to all customers at the highest possible level and not offer any discounts or special pricing arrangements.

Re-Setting the Non-Excessive Average Price After Introduction

The present solution still does not recognize the concern of stakeholders.

The proposed provision is not appropriate since it does not recognize that patentees are often faced with a variety of requests from provincial governments, health care providers and patients to make drugs available under the Special Access Program (SAP) at no charge or at a low price. Drugs sold under SAP are often not funded under government plans.

Essentially, the current proposal will not allow for re-setting in these circumstances and will force manufacturers to charge the full commercial price on SAP sales to the detriment of patients. Something the PMPRB has mentioned on several occasions that it expressly wanted to avoid along with the repeated stated objective not to limit or prevent the offering of a benefit.

Rx&D recommends that patentees provide the required product information once a Notice of Compliance has been issued by Health Canada.

Recognizing Benefits (DIP Methodology)

Rx&D appreciates the PMPRB has introduced a methodology that will allow for price adjustments based on the offer of benefit/contract or other type of support by a patentee.

In the context of running and operating the day-to-day business, the implementation and the management of this proposal will be a challenge. The PMPRB and patentees will have to create a system that tracks what the actual rebound level will be in 17 different markets especially if there are multiple contracts occurring across several provinces and customers, expiring at different times.

Essentially, it is not clear as to how it will actually function. For example:

Year 1	Non-Excessive PMPRB Price = MAPP at Launch	$10
Year 2	Price With Benefit	$8
Year 3	Price With Benefit	$8
Year 4	Price With Benefit but Expires Year End	$8
Year 5	Price DIP Rebound	$10

It is not clear if the Year 5 price is the new benchmark price. If it is not, based on the Consumer Price Index methodology, patentees in future years will run afoul of the Guidelines based on the 3-year price test which will result in a lower price than the re-adjusted non-excessive price in Year 5. The PMPRB is encouraged to clarify this point in the guidelines to ensure that the Consumer Price Index methodology does not undermine the intended outcome of the DIP methodology.

In addition, it is not clear why the PMPRB decided to exclude the Consumer Price Index increase during the period of the contract. It is highly unlikely that within this class would be covered or accept a single contract, hence some may see a Consumer Price Index based price increase over a multi-year contract period.

For example, a product is initially offered for sale at $1.00 to a province, but through a contract or agreement, the price is dropped to $.80 with rebates being provided. Once a contract ends, the patentee can then return to $1.00 without penalty.

However, if during the period of the contract, several allowable price increases had taken place in other provinces (e.g. up to the price of $1.06), the province where the initial contract was offered, would only be allowed to return to the $1.00 and not the $1.06. In effect prices are "frozen" during the period of the contract in that province. Shouldn't prices be allowed the price the PMPRB deemed to be non-excessive. For example, how could a price in one market be non-excessive at one price, but be excessive in another?

The threshold to which a price may return is calculated based on market level pricing. The Board definition of market does not distinguish between tender and non-tender markets.

Rx&D would recommend that the market specific ATP where benefits had been offered be allowed to increase up to the highest previous ATP with the inclusion of the increase in the Consumer Price Index in that market without being presumed to be excessive.

Finally, the PMPRB has not provided further clarity on the definition and description of benefits.

Offset of Excessive Revenues

The new proposal appears to be punitive given it is removing a previously acceptable option. The current provision of allowing to offset excessive revenues by either deferring or taking a less than maximum allowable price increase does allow a patentee to manage its market responsibilities in a logical manner that also protects the consumer. The PMPRB has mentioned on several occasions that the changes to the guidelines would allow for greater pricing flexibility. However, the current proposal would remove any pretext at pricing flexibility.

Policy for When a Price May be Considered Excessive

The new wording suggested is troubling. By stating on the PMPRB web site that a drug product "Appears Excessive" is misleading and automatically presumes guilt. It is not clear as to the rationale for such a change. The problem is further compounded given the lack of clarity in how the DIP methodology will function. Potentially, there could be cases were a product might "appear excessive" but upon further investigation is actually within the guidelines.

Such a statement will cause unnecessary confusion for its stakeholders as to what is excessive and what is not. In addition, such a proposal is contrary to recommendation made by the Working Group on Price Tests. Their suggestion was that the language should read: "Prices Under Investigation". Should the PMPRB find this wording not acceptable, other considerations could be "price monitored" or "price under review".

General Observations

The industry remains concerned about the regulatory burden these new guidelines will impose on both the PMPRB and patentees. Clarity regarding the technical elements is still required. While the PMPRB has engaged industry members at a senior level and explained various issues, there is still a strong concern regarding the practical implementation and application of these changes (i.e. the regulatory burden has actually increased rather than decreased).

How and when these guidelines will be implemented are still of concern to Rx&D. The PMPRB has made it clear that the new guidelines are effective July 1, 2009, and yet, there are no transition measures offered for examination. As mentioned above, there are many questions that must be clarified. For instance, there is currently a Judicial Review examining the PMPRB's jurisdiction regarding the reporting of benefits. It is very likely that a decision will not be reached by the Federal Court until after July 1, 2009. Once a decision is reached, there is a realistic possibility that the PMPRB will have to amend the guidelines once again.

Therefore, Rx&D recommends the PMPRB establish the new guidelines starting in 2010. This would go along way in helping industry and the PMPRB in preparing itself and working out all of the complex details. There are approximately only 20 days between when the guidelines are announced and when they are implemented. Calculating altered price tests based on a mid year reporting period will create confusion and difficulties. A full reporting period would allow for greater understanding and adaptability.

Rx&D understands that PMPRB's primary mandate is to ensure prices are not "excessive". However, the broader consequences of these changes need to be considered. Rx&D's membership is facing a period of consolidation and severely intensified global competition for R&D investment. Our members are our country's most passionate advocates on the global stage for investments to be made in Canada. The directions these guidelines are heading will not make it any easier for our member companies to bring investment to Canada.