Submission by

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

to the

Patented Medicine Prices Review Board

Follow-up to the Bilateral Meeting of September 11, 2007

THE CONTEXT FOR THESE CONSULTATIONS

The bilateral meetings between the Patented Medicine Prices Review Board (PMPRB, or the Board) and Rx&D and other stakeholders during the week of September 10, 2007 took place at a time of an unprecedented level of activity involving the PMPRB and pharmaceutical patentees. Although the purpose of the bilateral meeting was to discuss the Board's ongoing review of the Excessive Price Guidelines (Guidelines), there are a number of other outstanding issues that contribute to the broader context.

These consultations began 16 months ago with the issuance of the PMPRB's Discussion Guide in May 2006. The Rx&D Response to the Discussion Guide, of August 25, 2006, sets out our views on the questions raised at that time and the broader issues with respect to the PMPRB's mandate and regulatory expansion. We wish to remind the Board of that Response and incorporate it as part of our submission at this time.

Communications Between the PMPRB and The Regulated Industry: Pharmaceutical Patentees

In recent months there has been a marked increase in the frequency of interactions between Rx&D and the PMPRB which we consider to be a positive step. Pharmaceutical patentees are the only stakeholders of the Board subject to its regulatory oversight and therefore are the principal stakeholders. We appreciate the opportunities for dialogue and encourage the Board to continue in this direction.

In particular, we have appreciated the opportunity for direct "Board to Board" meetings and consider this to be an appropriate mechanism for the PMPRB and Rx&D to identify the broad pricing policy and operational issues that face the PMPRB and to discuss the agenda for future dialogue and work. We congratulate the Board on this initiative and encourage an ongoing dialogue through regular semi-annual Board to Board meetings in the future.

Another positive step has been the creation of the PMPRB Staff and Rx&D PMPRB Subcommittee working group. We hope that ongoing dialogue and consultations through this group will help to address many of the questions and concerns that arise on both sides from time to time and to provide an ongoing vehicle to identify and resolve issues at an early stage.

Proliferation of Issues

Recently, there has been an increase in the number of pricing policy issues under review by the PMPRB and issues on which the PMPRB and pharmaceutical patentees have differences of opinion. These issues are undoubtedly of concern to the Board as it attempts to fulfill its mandate under the *Patent Act* (the *Act)* and are also of concern to patentees as they seek to plan and carry out their business activities to the benefit of Canadians and in compliance with the law.

At present, there are so many issues on the table that the patented medicine price review system in Canada is creating an added uncertainty for manufacturers that impedes positive and long term business planning. We are concerned that a continuation of this environment will have a negative impact on the development and introduction of new medicines in Canada, to the detriment of Canadians and our health care system, and we encourage the Board to attempt to resolve these issues as quickly as possible.

In addition to the issues raised in the consultations on the Guidelines, we note the outstanding questions concerning the interpretation of the Federal Court decision in the DOVOBET case, the proposed amendments to the *Patented Medicines Regulations, 1994* and the Board's statements in the April 2007 NEWSletter concerning confidential agreements between manufacturers and provincial governments.

It appears that the PMPRB is attempting to address these issues in silos. While we can appreciate the need to ensure a manageable process, we are concerned that this approach may fail to provide an adequate means to recognize the linkages among the issues. In fact, it is counterproductive to attempt to discuss some of these issues in isolation as they are so inherently linked to one another. For example, questions about the implications of the DOVOBET case have a bearing on proposed revisions to the *Patented Medicines Regulations*, and on several of the issues in the consultations on the Guidelines, such as the issues pertaining to "re-benching" and the meaning of "any market."

Therefore, while this submission addresses the questions that the Board has raised in its *Stakeholder Communiqué* of May 31, 2007 with respect to the review of the Guidelines, we wish to emphasize that we consider that many of these issues have implications for other questions that are currently under consideration or are the subject of separate discussions with the Board at this time.

The Need to Respect the PMPRB's Mandate

As noted in its previous submission, Rx&D and its member companies are concerned by initiatives of the Board that appear to keep moving it further away from its original mandate as established by Parliament through the *Act*.

Over the years, the PMPRB has evolved from carrying out an oversight role with respect to patented medicine prices to a more direct role in the day to day business activities of patentees. Rx&D remains concerned that many of the issues under review through the consultations on the Guidelines, along with other issues that have been raised in recent years, represent an attempt by the Board to intervene in the pharmaceutical market in ways that were not contemplated by Parliament and the *Patent Act* and which are unnecessary to the carrying out of the Board's mandate.

In particular, it is our view that the Board has not been consistent with the spirit of its mandate under the *Act* by causing prices of patented medicines in Canada to remain consistently below the median of international prices for more than a decade. The *Act* establishes the appropriate objective or threshold that Canadian prices for patented medicines should not be excessive. On that basis, and in light of the price determination factors in subsection 85(1) of the *Act*, it would be reasonable to conclude that Parliament intended that prices for patented drugs in Canada not exceed the range of prices in other countries and the CPI-adjusted prices of all other drugs in the therapeutic class. The Board's expansive interpretation of its mandate has resulted in policies which have clearly exceeded this goal.

The PMPRB's activities in recent years have also suggested that it has lost sight of the intention of the amendments to the *Patent Act* in 1987 and 1993 to encourage and foster innovation in the pharmaceutical sector. The Board's Guidelines have historically failed to provide an adequate recognition of the value of innovation in new drug development. A number of the issues under review today threaten to introduce more barriers to investments in innovation in Canada by creating market uncertainty and new impediments to firms to bring products to market at appropriate prices.

THE CONSULTATIONS ON THE EXCESSIVE PRICE GUIDELINES

General Comments

The PMPRB initiated the current consultations 16 months ago with the release of its Discussion Guide in May 2006. Since then, Rx&D and its member companies have participated actively in the ongoing consultations through written submissions in 2006, participation in the public meetings in the fall of 2006, and the bilateral meetings with the Board in September 2007.

Over this time, Rx&D has been concerned that the Board has not indicated a clear purpose or objective to its review of the Guidelines and has not established a timeframe

for its completion. In the fall of 2006 and once again in the spring of 2007, the Board significantly expanded the scope of the consultations by adding more issues to the review. As a result, many aspects of the Guidelines are now under study, which in turn causes uncertainty for patentees with respect to the regulatory environment that they will be facing in late 2008 and future years.

Rx&D is concerned that the review of the Guidelines by the Board has become increasingly unfocused over time, that it now covers too many issues to be reasonably considered at one time.

Patentees are also concerned that some of the issues have been included in the consultation despite the fact that they are theoretical rather than practical in nature. For example, and by its own admission in the May 31st *Stakeholder Communiqué*, no situation has ever arisen where the cost of "making and marketing" has had to be considered by the Board in making an excessive pricing determination. Patentees question whether the fact that something may arise at some future point in time justifies an expenditure of time and resources by the Board and stakeholders during the present consultation process.

Pharmaceutical patentees are also becoming more concerned that this review, coupled with the other ongoing issues, suggests that the Board is seeking to exercise greater surveillance over their activities and to introduce more stringent price controls. As noted, these circumstances create considerable uncertainty for patentees which may affect their decisions to bring new products to market.

We strongly encourage the Board to streamline the review of the Guidelines and establish a clear and public timetable with decision points for the completion of this project.

Principles

The Board proposes to include language in the preamble to the Guidelines to this effect:

> The Board's mandate is to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive, thus protecting the interests of consumers.

The PMPRB has used similar language in other circumstances in the past, but it has not used it in the Guidelines. The Board's purpose in proposing this change at this time is not clear. The mandate of the Board is spelled out in the *Act* and needs no elaboration. Section 83 provides that:

> Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells the

> medicine in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.

The *Act* makes no reference to consumer protection. Even if it did, consumer protection is fostered not only by non-excessive prices but also by innovation in pharmaceutical treatment; by research and development into new therapies; by the speedy introduction of new medicines; and by access to the widest range of medicines to treat diseases and improve health.

The *Act* is intended to encourage innovation by rewarding inventors through the patent system. The Board's role is to ensure that pharmaceutical patentees do not abuse the exclusive rights they receive from a patent by charging excessive prices.

Rx&D does not believe that it is necessary or helpful to include consumer protection language in the Guidelines. However, if the Board considers it necessary to include a reference to "consumer protection" in the Guidelines, such language should be balanced by appropriate references to the objective of promoting and encouraging innovation and investments in the biopharmaceutical sector.

Categories

The Board proposes to continue to pursue questions related to the appropriate categories of new medicines for price review purposes by establishing a working group to develop definitions related to "breakthrough," "substantial improvement," "moderate improvement," and "little or no improvement."

Rx&D continues to have many reservations about the current categories and definitions used by the Board as they do not adequately recognize the therapeutic value a new medicine may offer. The definitions of "breakthrough" and "substantial improvement" are too restrictive. The PMPRB has frequently declined to categorize new drugs as breakthroughs or substantial improvements, contrary to the use of comparable designations by international bodies, and despite evidence that has led Health Canada to assign priority review status to those medicines.

Similarly, the inclusion of drugs offering "moderate, little or no improvement" in one category has resulted in an inappropriate price standard that limits the price of a new drug to existing drugs in the class regardless of the incremental value it may offer. This fails to recognize the value of many new drugs and sends the message internationally that Canada's price review system does not value incremental innovation.

Furthermore, the questions of categories and the appropriate price tests are inextricably linked. In its submission in August 2006, Rx&D proposed an appropriate excessive price test that would apply for all new drugs, thereby removing the need for categories. The Board has not responded to Rx&D's proposal for an appropriate price test. We continue to be of the view that a price test based on the statutory standard of "excessive" and the

factors in the *Patent Act* does not require the categorization of new medicines currently used by the Board.

Some non-patentee stakeholders make references to the categorization of new medicines by the PMPRB without a full appreciation of the purpose of the categorization. The PMPRB's Guidelines use categories solely for purposes of price review. The PMPRB's categorization does not, and should not, detract from the decisions to give marketing approval by Health Canada based on evidence of safety and efficacy, nor the prescribing decisions of health care professionals based on their considered assessment of the needs of the patient.

Our proposal addresses the issue of the appropriate excessive price test for patented medicines and also addresses the concern that the current Guidelines do not adequately recognize the value of incremental innovation in the development of new medicines. It offers a reasonable balance between meeting the objectives of the *Act*, while allowing a measure of flexibility for patentees to establish prices in response to market conditions. It also addresses the existing problems with the definitions and categories of new medicines used by the Board.

In considering the question of categories, we urge the Board to take the following into account:

- The current Guidelines rely on definitions and criteria for "breakthrough" and "substantial improvement" that are too narrow and are out of step with standards used elsewhere;
- They do not adequately address the incremental improvement offered by many new medicines;
- If the Board adopts an appropriate excessive price test, there is no need for categories; and
- The Guidelines should not restrict the price of a medicine which offers an improvement in therapeutic effects to the prices of existing medicines.

In our view, it is not practical to debate definitions of the degrees of therapeutic improvement for price review purposes without developing a shared view on the merits of recognizing incremental improvement through an appropriate price test that permits a price higher than the existing drugs in the class.

The issue of categories is significant to the review of the Guidelines, and if the Board decides to pursue the plan to establish a working group on this issue, Rx&D welcomes the opportunity to take an active part.

International Therapeutic Class Comparison

The PMPRB introduced this question to the review of the Guidelines in the spring of 2007. It is not clear what concern the Board hopes to address, or whether it proposes to introduce new Guidelines in future related to this issue.

Section 85(1)(c) provides that one of the factors the Board shall take into consideration in determining if a price is excessive is:

> the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada.

This factor may be raised in the context of an excessive price hearing and the Board is in a position at that time to consider and assess the relevant evidence and put the appropriate weight on it. There are a number of circumstances where evidence with respect to the international therapeutic class comparison may be relevant for these purposes, but it is difficult to generalize those circumstances for purposes of establishing Guidelines that will apply to all patented medicines.

Rx&D notes that the PMPRB has, in a small number of cases, resolved pricing disagreements with patentees by taking into account relevant information with respect to international therapeutic class comparisons and has used this factor in a flexible way to resolve disagreements with patentees. We believe it is appropriate, where a price may appear to be outside the Guidelines, to do further analysis of the international therapeutic class for that medicine, but that such analysis is best conducted on a case by case basis.

On balance, the need for a Working Group on this issue remains unclear, but if the Board decides to pursue that approach, Rx&D will participate in the process.

Price Tests

The Board has indicated that it is reserving comment on price tests at this time as a result of the decision to establish certain working groups.

As noted above, Rx&D is of the view that the price tests are inextricably linked to the other questions with respect to the Guidelines. Accordingly, we are very concerned that it will be difficult to achieve consensus on other issues (notably with respect to any changes to the present categories) in the absence of a clear direction of the implications for the price tests under the Guidelines.

Costs of Making and Marketing

The Board introduced this issue into the consultations in the spring of 2007. In doing so, it acknowledged that "it has not had to give consideration to subsection 85(2) [of the *Patent Act*] to make a determination of excessive pricing." As noted above, Rx&D does not understand why the Board has raised what appears to be a largely hypothetical issue at this time.

We are pleased to note that the Board Staff have indicated the Board's intention not to proceed with the initial plan to establish a working group on this issue. However, given

its hypothetical nature, Rx&D does not believe that any changes to the Guidelines pertaining to this issue are needed.

Price Increases

The Board has indicated that it proposes to draft language to permit greater flexibility in applying the existing CPI methodology in rare circumstances where the maximum non-excessive (MNE) price calculated under the Guidelines is less than or equal to the average transaction price of the previous year which was within the Guidelines.

We look forward to seeing the proposed language for consultation, and suggest that the Board provide specific examples of the "rare circumstances" to which it refers.

Adjusting the Benchmark Price (Re-benching)

The Board has indicated that it considers it appropriate to give further consideration to circumstances where re-benching may be appropriate, including but not limited to the two situations already identified in the Guidelines. Those two situations are:

- When a new drug being sold under the Special Access Program (SAP) is granted a Notice of Compliance (NOC); and
- Where the median international price comparison sets the MNE price and the drug is sold in less than five countries; in this case, it may be appropriate to re-bench the MNE price when the drug is sold in five countries or after three years, whichever comes first.

The Board has traditionally dealt with such issues on a case by case basis. Again, Rx&D would encourage the Board to provide more information on how it proposes to review this question. In the absence of further information, Rx&D is opposed to any expansion to the current two re-benching criteria, given such expansion is potentially a source of significant commercial uncertainty for patentees.

Any Market

The Board has indicated that stakeholders are of the view that to the extent that any review should be conducted at the level of "any market" rather than on the basis of a national average price, the review should be undertaken only where warranted and on a case by case basis. The Board states that it will be identifying circumstances "where it may be appropriate to review prices in any market."

Rx&D is opposed to any change from the current national ATP definition. The current national definition is the most efficient and preferable definition. The Board has not to date identified any such circumstances and has not demonstrated the need to pursue this issue further. In addition to being inefficient and unjustified, Rx&D also believes that any change to consider sub-national markets is inconsistent with the PMPRB's mandate as a Canadian national oversight body making its determinations based upon an examination

of Canadian patented medicine pricing relative to the designated international comparator nations set out in the *Act*.

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Conclusion

Rx&D has been concerned by the increasing number of pricing policy issues that have arisen between the PMPRB and pharmaceutical patentees, and is appreciative of the efforts of the Board to attempt to improve ongoing dialogue to help address these issues.

Among other things, Rx&D believes that pharmaceutical patentees are not simply a "stakeholder", but that they have considerably more interest in the manner in which the PMPRB carries out its mandate because of its very significant impact on their day to day business activities and long term investment decisions. We welcome the opportunity to develop ongoing dialogue through Board to Board meetings and through the working group of PMPRB Staff and the Rx&D PMPRB Subcommittee.

The number of contentious issues and their potential significance has created considerable uncertainty for patentees. Rx&D therefore encourages the Board to move quickly to consolidate the outstanding issues and establish a work plan to proceed with them. We also encourage the Board to take account of the linkages between the many issues under consideration in this process.

Rx&D is committed to continue to work with the Board to assist in fulfilling its mandate through stable and predictable policies consistent with the objectives of the *Patent Act* to prevent excessive pricing while encouraging innovation in the Canadian biopharmaceutical sector.