Canada's Research-Based Pharmaceutical Companies (R&D) Les compagnies de recherche pharmaceutique du Canada

President's Office / Bureau du Président

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September 30, 2008

Dr. Brien G. Benoit
Chairperson
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
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Doc. 004720

Dear Dr. Benoit:

On behalf of *Canada's Research-Based Pharmaceutical Companies* (Rx&D), I am writing in response to the PMPRB's Notice and Comment package on the Draft Revised Excessive Price Guidelines released on August 20, 2008 and in response to your letter of September 24, 2008.

Rx&D and its member companies have participated fully in this consultation process since it was initiated in May 2006, but we are disappointed and surprised that the Board has overlooked the significant feedback we have provided through written submissions, face-to-face meetings and the Working Groups. Many of the latest proposals are unworkable and fail to recognize the complex and dynamic nature of the pharmaceutical industry in Canada.

The PMPRB has not been clear on the purpose and objectives of these consultations nor has it provided a rationale for the proposed changes. Its Annual Reports have not identified problems with the Guidelines; on the contrary, the Board has consistently reported a high rate of compliance and stable prices for patented medicines that fall in the mid-range of prices in other countries. Given this track record, the need for the proposed expansion of price controls has not been demonstrated.

The proposals represent an unprecedented intervention in the pharmaceutical market. They would introduce a degree of price control that is unequalled in any other sector of the economy. They are inconsistent with the policy objectives of the pharmaceutical pricing provisions of the *Patent Act* and contrary to economic theory and the incentives that create dynamic growth in this important sector of the economy. The proposals would create an additional regulatory burden for patentees that runs counter to the policy objectives set out in the federal *Cabinet Directive on Streamlining Regulation* issued on April 1, 2007.

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Worse, the proposals will have the unfortunate effect of discouraging the offering of compassionate access programs for patients, putting upward pressure on prices, and limiting competition among patentees. The attached appendix provides more extensive comments on the elements of the proposed changes and illustrates the reasons for these unintended effects.

A further problem with the proposals is that some of them are overly-complicated and many elements are vague or have not been addressed. Even after technical briefings for stakeholders by PMPRB staff in September, important questions remain about how the provisions would be applied on a day-to-day basis. These questions are also addressed in the appendix.

We are concerned by the unpredictable and unfocussed approach taken by the PMPRB in recent years. The lengthy consultations on the Guidelines, the lack of consensus on the reporting requirements under the Regulations and the increased reliance on contested hearings rather than dispute resolution, have created uncertainty and instability that affects business planning and makes it more difficult to attract global investment for research and development in Canada.

Despite all the hard work by the Board and its stakeholders, the consultation exercise has failed to achieve the necessary measure of consensus to support moving ahead at this time. Given that both the August 18th Communiqué and the proposed changes to the guidelines are interrelated, we respectfully ask the Board to defer implementing the Communiqué until the final outcome of the judicial review, and from adopting changes to the guidelines since further review and analysis is required.

We accept your invitation for a meeting of our respective Boards on October 21, 2008. We feel that this will be an excellent opportunity for the leadership of the industry to meet with Board members to have a broad dialogue about the role and mandate of the PMPRB. By coming to a common understanding of the mandate of the PMPRB, we can then work together to ensure that the implementation of the mandate continues to respect the terms of the Patent Act while ensuring that Canadians have access to innovative medicines.

Sincerely,

Russell Williams
President

c.c. Sylvie Dupont, Secretary of the Board, PMPRB

Appendix: Rx&D Technical Submission to PMPRB

This submission is organized in accordance with the PMPRB's Notice and Comment package on the draft revised Excessive Price Guidelines released on August 20, 2008. It includes comments and recommendations on the issues in the order they appear in the document and, in addition, we have identified some issues that have come to light as a result of a review of the draft Guidelines.

This submission identifies many of the concerns and recommendations of Rx&D and does not necessarily reflect all of the concerns of our members. In light of the complexity and scope of the proposed revisions, it is possible additional concerns will come to light and we will wish to make further submissions.

Issue - Underlying Principles

Among the changes proposed in the draft revised Guidelines is to include this language in the description of the Board's regulatory mandate in Section I, paragraph 2.1, page 2: "… thereby protecting consumers and contributing to Canadian healthcare."

This language does not appear in the *Patent Act* and represents a statement that the Board has read into its mandate. Use of similar language in the past may have caused some stakeholders to misinterpret the role of the Board when they suggested some of the "principles" quoted in the document.

The primary purpose of the pharmaceutical provisions of the 1987 *Patent Act* amendments was to improve protection for pharmaceutical patents and encourage innovation in the sector. The purpose of establishing the PMPRB was to maintain an appropriate balance between the incentives for pharmaceutical research and development and protection against excessive prices.

Recommendation:

Given the potential for misinterpretation of the Board's mandate, Rx&D recommends that the Board not include "… thereby protecting consumers and contributing to Canadian healthcare" in its mandate statement in the Compendium.

In the alternative, if the Board believes that some language is appropriate, it should revise the phrase to read: "… thereby maintaining an appropriate balance between the incentives for research and development and protection against excessive prices."

Issue - Levels of Therapeutic Improvement

It is Rx&D's position that there is no need for the PMPRB to distinguish levels of therapeutic improvement for purposes of applying the pricing provisions of the *Patent Act*. In our view, a proper test of excessive price does not require drawing distinctions

between drugs based on an assessment of therapeutic improvement. We have made previous submissions on this point, including a proposal for an appropriate excessive price test. The Board has not provided a clear response to those submissions.

The comments below highlight some of the challenges created by relying on assessments of therapeutic improvement.

Overlap and Duplication: One of the difficulties of using a hierarchy based on therapeutic improvement is the need to conduct a scientific evaluation to assess therapeutic improvement. The PMPRB has traditionally used the Human Drug Advisory Panel (HDAP) for this purpose and now plans to expand its responsibilities.

The therapeutic evaluation by the PMPRB is an unnecessary duplication of work undertaken by Health Canada which is the federal body with statutory responsibility for assessing the safety and efficacy of new drugs in Canada. Furthermore, it is up to the Common Drug Review (CDR) and provincial drug plans to evaluate the cost-effectiveness and reimbursement status of new drugs. The work of the HDAP for purposes of the PMPRB's Guidelines requires the PMPRB to maintain an additional and unnecessary overhead.

Assessment of therapeutic improvement by the PMPRB not only duplicates work done by others, but also raises the potential for conflicts. It is our understanding that many of the disagreements between the Board Staff and patentees revolve around disagreements about HDAP recommendations. For example, the HDAP does not acknowledge decisions by Health Canada to grant a new drug a Priority Review in making its recommendations even though the criteria for Priority Review approximate those for "breakthrough" and "substantial improvement" drugs. These conflicting positions contribute to a lack of certainty on the part of patentees, and therefore potential disputes, and also lead to confusion on the part of patients and other stakeholders.

The work of the HDAP should be limited to recommending appropriate comparators and dosage regimens for purposes of therapeutic class comparisons.

Four Levels of Therapeutic Improvement: While we do not see the need for the PMPRB to establish levels of therapeutic improvement, we agree in principle that the proposal to establish a fourth, "moderate improvement," level with an appropriate price test represents an advance over the current three categories used by the PMPRB.

The current categories do not recognize the value of incremental innovation even though such drugs have an important role in meeting patient needs, improving health outcomes and paving the way for further advances.

Criteria For Assessing Therapeutic Improvement: We are also supportive of the consensus recommendations of the Working Group on Therapeutic Improvement (WG-TI) to define criteria to be taken into account by the HDAP in making its assessment. We

are concerned though by the decision of the Board to accept only some of those recommendations and reject others.

In particular, we are concerned by the Board's apparent rejection of the recommendation of the WG-TI to include economic factors as one of the factors to be considered in determining therapeutic improvement. The current Guidelines provide that a substantial improvement drug is one that:

> *provides substantial improvement in therapeutic effects (such as increased efficacy or major reductions in dangerous adverse reactions) or* ***provides significant savings to the Canadian health care system****.* (emphasis added)

The WG-TI proposed maintaining the consideration of economic factors in determining therapeutic improvement and expanding it to include savings "to patients and/or caregivers." It proposed this language:

> *... savings to the Canadian healthcare system (private or public payers and employers) and/or to patients and/or caregivers.*

Instead, the Board has proposed demoting economic factors to be secondary factors and rejected inclusion of savings to patients and/or caregivers.

The Board has also rejected the WG-TI's recommendation to include patient compliance as a stand-alone factor by adding the requirement to demonstrate that the improved compliance leads to improved therapeutic efficacy.

Rx&D is concerned that introduction of the proposed levels of therapeutic improvement, and need for the Human Drug Advisory Panel to establish experience in applying the definitions and criteria, will create considerable uncertainty and compound the existing lengthy delays in the review process by the PMPRB.

Recommendations:

We recommend that the Board reconsider the need for assessing therapeutic improvement as part of a package of examining ways to simplify its Guidelines proposals and approach to fulfilling its mandate.

Until it does so, we recommend proceeding with the proposal to establish a "moderate improvement" category for price review purposes provided that the price test provides greater flexibility than currently exists for such drugs.

The HDAP should place greater reliance on the approvals by Health Canada and not make recommendations that appear to be at odds with those of the regulator.

We ask the Board to reinstate the appropriate consideration of savings to the health care system in assessing therapeutic improvement and that it adopt all of the consensus recommendations of the WG-TI.

Issue - International Therapeutic Class Comparison (ITCC) Test

Rx&D agrees with the thrust of the PMPRB's proposal that the ITCC will not normally be used as a price test for a new patented medicine but should be used to the extent that it may aid in resolving a dispute with a patentee prior to the referral to the Board for a hearing. It is our understanding that this is consistent with the PMPRB's informal practice in the past.

The Board appears to have substantially adopted the consensus recommendations of the Working Group on International Therapeutic Class Comparison (WG-ITCC) but the proposed Schedule 7 to the revised Compendium does not address all of the recommendations. In particular, the proposals do not include this recommendation:

> *5.5 The WG-ITCC further recommends that generic drugs should not be included in the ITCC if the Board decides that the determination of the maximum non-excessive (MNE) price will be established by using any measure below the "top" of the ITCC.*

The proposed ITCC Guideline does not specify that if the ITCC is used the MNE price will not be established at a level below the "top" of the ITCC.

Recommendation:

The Board should amend the proposed Schedule 7 to exclude generic drugs from the ITCC.

Issue - Introductory Price Tests

It is Rx&D's submission that the introductory price of a new patented medicine should only be considered excessive if it exceeds the prices in all other countries and the CPI-adjusted prices of all other drugs in the therapeutic class. Market forces, including reviews by the Common Drug Review and provincial committees, and the reimbursement decisions by public and private plans, will all go toward ensuring that prices will fall below that excessive price threshold.

We are concerned by the absence of several key provisions of the current Guidelines in the revised text, including provisions governing the Reasonable Relationship (RR) test and the TCC test. The front portion of the Notice and Comment document, setting out *Board Positions*, does not refer to these omissions or provide any rationale for them. There has been no prior notice and no opportunity for consultation on these important proposed changes to the Guidelines.

Although the text of the Notice and Comment states that "It is also agreed to maintain the RR test for line extensions where no therapeutic improvement is proposed," the draft Guidelines includes these significant changes:

- In Test 3: Different Strength Test, the existing provisions for a new DIN of a lower strength have been omitted. They provide that the price of the new DIN cannot exceed the price of the existing higher strength DIN. This test makes sense and is consistent with the other provisions of the RR test. Through omission, the draft revised Guidelines would introduce a new and unreasonable standard for a new DIN of a lower strength requiring the price to be directly proportional on a price/kg basis to the existing DIN.

- The draft Guidelines have deleted an existing provision that provides an alternative when the RR test is not appropriate; this provision should be reinstated to provide greater clarity:

> *8.3 .... When the above methodology is not considered adequate or appropriate, Board Staff may conduct a Therapeutic Class Comparison Test (Schedule 2) to determine if the introductory price of the new DIN is excessive. This could be relevant if, for example, the new DIN has a therapeutic use or dosage regimen that differs materially from the other DINs of the same or comparable dosage forms of the medicine.*

- The draft has also removed the specific provisions of the Guidelines for modified release formulations.

The draft Guidelines have also omitted a key provision that provides an alternative when the Therapeutic Class Comparison Test is not appropriate:

> *8.6 When it is inappropriate or impossible to conduct a Therapeutic Class Comparison Test, Board Staff will give primary weight to the median of the international prices identified in an International Price Comparison Test (Schedule 3) to determine if the introductory price of the new DIN is excessive.*

All of these provisions should be reinstated.

Measuring the Price in a TCC: The proposed Guidelines state that Board Staff will use an "appropriate public source for the prices of comparable products" to be determined on a case-by-case basis. This proposal is too vague and provides an inadequate measure of certainty for patentees attempting to establish their prices within the Guidelines. A more appropriate standard would be the highest publicly-available price for the comparable products. This concept would provide greater certainty 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.

Recommendations:

We recommend that the Board amend the draft Guidelines to re-incorporate these provisions from the existing Guidelines:

- RR: the existing different strength test,
- RR: the existing alternate test (TCC) where appropriate,
- RR: the specific provisions for modified release formulations,
- TCC: the existing alternate test (IPC) where appropriate.

We also recommend, to be consistent with a recent Board decision, that in Schedule 4, "Measuring the Price", the third paragraph should be amended to read: "For comparison purposes, Board Staff will use the highest publicly available prices for the comparable products."

Issue: Impact of Reporting Benefits (De-linking of the ATP from the MNE Price)

As part of its submissions during the consultations Rx&D has encouraged the Board to consider an alternate model of price review that would involve de-linking the MNE price from the ATP. In our view, such an approach would go a long way to reduce and even eliminate many of the operational problems that the Board is trying to fix through some of the proposed Guidelines changes.

It is Rx&D's submission that the Board should replace its current CPI-adjusted methodology with a true de-linked price review model, i.e. a model whereby the Board reviews prices with reference to the MNE price adjusted for changes in CPI, as opposed to the current model whereby the Board reviews prices against a previous net ATP adjusted for CPI. This model is consistent with the objectives of the *Patent Act* and would introduce greater clarity and efficiency to the price review system.

While it is positive that there was some progress on this topic through the Working Group on Price Tests (WG-PT), we are disappointed that the Board's proposal does not even go as far as the WG-PT proposed and that it also introduces more complicating factors.

We are concerned by the failure of the Board to attempt to address the issue through the "gap" methodology proposed by the WG-PT. In our view, these elements constitute a package and should be adopted together.

The intention of the "gap" proposal by the WG-PT was to recognize the difference between the MNE price and ATP at launch and to reduce the disincentives to offer a lower ATP because of the CPI methodology. Given the lack of clarity on "benefit," "market forces," and other terms used by the Board to explain pricing below the MNE price, the "gap" proposal represents a compromise to allow some measure of flexibility that will not allow a price that exceeds the MNE price established by the Board.

It is our understanding that the Board has concerns about the potential for large one-year price increases under the "gap" methodology. The WG-PT proposed a formula to address that concern: to limit a single year increase to 33% of the price gap provided it does not exceed 10% or 15% of the ATP. Under these scenarios, the maximum allowable price would continue to be well below the MNE price established by the Board for at least two years and it would take between three and ten years before a price could reach the level that the Board's Guidelines determine to be the maximum non-excessive price.

Rx&D remains concerned that the manner in which the PMPRB staff plan to apply the "dip" methodology will create a high volume of operational difficulties and does not reflect the real world. The proposed application of the "dip" concept, as described in staff briefings held in September, has the potential to become a bureaucratic and regulatory nightmare. The examples provided by the Board Staff are attached. They illustrate the complexity of the model and show how it produces results that are inconsistent and difficult to explain.

Although the model is overly-complicated, the assumptions made are overly-simplistic and do not reflect the real pricing and reimbursement system in Canada. The Board's examples suggest that a patentee only offers a rebate or benefit to a particular market segment during a particular calendar pricing period. The reality is substantially different. There may be a variety of offers and benefits that are taken up by some customers and not others over different periods of time. There are multi-year contracts that may not be based on the six- or twelve- month reporting periods used by the PMPRB. They may involve volume purchasing. They may involve national compassionate programs that are administered on a patient basis rather than on a "by province" basis. They may involve bundling of other products and services. They may involve regional buying groups with different purchasing patterns.

As an industry association, we do not know all the types of purchasing arrangements that may be negotiated in a competitive market, but we believe they are much more varied than contemplated by the Board's examples. The Board's examples make no effort to disentangle the actual type of transactions that occur in the real world.

The standard proposed for de-linking is overly restrictive:

> *...when the ATP declines ... due to the provision of a benefit(s) and if once the benefit ends the patentee provides evidence to demonstrate that the price increase was due solely to the termination of the benefit.*

Given the complexity of the market and the potentially large number of individual transactions under different conditions to different customers, the narrow language proposed raises the potential for many disputes with patentees and the threat of an increased number of hearings.

There continues to be a lack of clarity on the Board's definition of "benefit related to a sales transaction." Patentees will not know before the introduction of a program if the Board will accept it as qualifying to be considered a "benefit" for purposes of the de-linking methodology.

This lack of guidance not only affects the future, but also the current situation. Patentees may be required to seek to apply the dip methodology as early as next year for drugs that have been on the market for many years. The Notice and Comment proposals offer no guidance on this point and no transitional provisions.

We are also concerned that the Board's proposal for de-linking only provides, once the Board Staff is satisfied the patentee has fulfilled the criteria, that the previous highest ATP will be considered the MNE price. Under the rationale for the "dip" methodology, this provision is overly restrictive as it would effectively impose a price freeze in that market. As such, it would add another disincentive to offering benefits in the first place. The appropriate adjustment would be to the previous highest ATP adjusted for changes in CPI over the relevant time period.

Collecting and maintaining the documentation necessary to satisfy the Board Staff in cases of de-linking and sales-mix shifts (see below) will require patentees to invest in new accounting and financial systems. It will also place an operational burden on the PMPRB and lead to further delays in the price review process and increased litigation.

Recommendation:

There is an urgency to address the de-linking issue as quickly as possible. Rx&D proposes that the Board establish a small committee with Rx&D to identify some interim measures pending a more thorough review.

Issue - Any Market Price Reviews

The PMPRB has not demonstrated the need to expand its regulatory activities to review prices "in any market." As the Board itself has reported in previous discussion papers, stakeholders have overwhelmingly indicated that they do not believe that the Board should review prices in any market on a regular basis but recognize that the Board always has the ability to do so on a case-by-case basis.

We are concerned by the decision by the Board to expand use of any market review for Guidelines purposes and by the inconsistent and vague language used in the Notice and Comment package.

There is inconsistency within the Notice and Comment package on the application of any market review for the introductory prices of new drugs. The Board's position is "that is important to ensure that introductory prices are not excessive for any class of customer or in any province/territory."

However, the draft Guidelines state:

> *3.10 In addition to the price tests described above, the introductory prices for specific relevant markets will be reviewed to ensure they are not excessive.*
>
> ...
>
> *3.15 Board Staff will calculate an ATP for each of three classes of customers (hospital, pharmacy and wholesaler) to ensure that the price for each class of customer does not exceed the national MNE price for the drug product.*

The document is also inconsistent and vague on the application of any market review for existing drugs and this raises even greater concern as it impacts the ongoing monitoring by patentees to ensure compliance with the Guidelines.

In its position, the Board states: "For existing drug products, the Board agrees that any market reviews only be carried out on a case-by-case basis ***where price variability in different markets appears to be an issue.***" (emphasis added) Leaving aside the question of how it will be determined if price variability appears to be an issue, this statement leaves the impression that any market review for existing drugs will be carried out on an exceptional basis, but other provisions suggest otherwise.

One reason for our concern on this point is that the draft Guidelines include a provision to apply any market review in the event of sales-mix shifts and the briefings provided by Board Staff in September (see Attachment) indicate an intention to use any market review in applying the proposed de-linking methodology even though there is no reference to doing so in the consultation package. As a result, we are concerned that any market reviews will be conducted in more frequent and unpredictable cases.

Rx&D is also troubled by the proposal to introduce the complex formula for reviewing prices in any market in the case of sales-mix shifts. There is no evidence to suggest that these provisions are warranted and in fact they will result in unfounded allegations of excessive pricing.

Recall that a sales-mix shift refers to changes in the mix of the volume of sales at different prices which causes the ATP to go up or down even if there is no change in the price paid by any customer. Proposed Section III, Chapter 3, paragraph 4.3 of the Guidelines (page 18) states that in these circumstances "none of the prices for each class of customer and in each province/territory" may exceed the CPI-adjusted national price. The CPI-adjusted price is based on the ATP, which in turn represents the average price to all customers. Since it is an average, some customers may have paid more and some may have paid less. By definition then, applying any market review in these circumstances will result in unfounded allegations of excessive pricing.

Similarly in the case of "de-linking," the examples provided by Board Staff indicate an intention to apply any market review when considering evidence from a patentee that an

apparent price increase was attributable to the termination of a benefit. There is nothing in the Board's Position nor in the Guidelines that suggest it is the Board's intention to apply any market review in these circumstances.

To apply any market review on a broad basis, given the current CPI-adjusted methodology, will create a continuing downward pressure on prices. Because of the inherent uncertainty and risk of running afoul of the Guidelines if they were applied this way, it will create incentives for patentees to maintain prices to all customers at the highest possible level and not offer any discounts or special pricing arrangements.

Recommendations:

This issue requires further work and analysis. The Board should clarify the problem it is seeking to address through any market review, determine the extent of the problem and assess potential solutions accordingly.

The Board should be more precise about what it is proposing and the intended impact.

In the event the Board applies "any market" review and finds a price is excessive, it should base the calculation of excess revenues on the national average transaction price.

Issue - Re-setting the MNE Price

Rx&D notes that the PMPRB has specifically retained the provisions for re-setting the benchmark price in the case of a drug, for which the median international price test is the relevant price test, that is sold in fewer than five countries at launch.

We also note that the existing provisions for re-setting the MNE price in the case of a drug being sold under the Special Access Programme (SAP) have been omitted from the draft revised Compendium:

> *4.2 The PMPRB recognizes that once a Notice of Compliance (NOC) has been obtained, it may be appropriate to adjust the benchmark price of a drug product first sold as an Investigational New Drug or under the Special Access Programme. In these cases, the average transaction price of the drug product following receipt of the NOC may be reviewed to determine if it appears to be excessive, based on the Guidelines applicable to new drug products.*

No explanation has been given for this change. In previous discussion papers, the Board has referred to examining "additional" circumstances for re-setting the MNE price and therefore we had understood this provision would be retained. There has been no consultation on the potential to omit this provision.

The existing provision is appropriate because patentees are often faced with a variety of requests from provincial governments, health care providers and patients to make drugs

available under SAP at no charge or a low price. Drugs sold under SAP are often not funded under government plans.

The existing provision recognizes that the inability to re-set the MNE price in these circumstances would force manufacturers to charge the full commercial price on SAP sales to the detriment of patients.

Recommendation:

The existing provisions on re-setting the MNE prices of drugs sold under SAP should be reinstated in the Guidelines and they should be applied on a regular basis by Board Staff.

Issue - Exchange Rates

The draft Guidelines include provisions, (Schedule 6, paragraph 5.1, p. 31) to require patentees to lower prices in the event of unusual factors in foreign markets:

- changes in exchange rates;
- price reductions due to a foreign regulator; and
- removal of a drug from the market in another country.

These provisions did not exist in the Guidelines in the past, and they have not been the subject of these consultations. Because of the dramatic changes in exchange rates in recent years, this question has become more significant than it was in the past. The proposals are not reasonable for several reasons.

First, Canadians are adequately protected from excessive pricing with reference to the foreign factor in the Act with the restrictions on the introductory price which take into account the foreign prices at that time.

Second, the price of the drug over time is already adequately restrained in Canada by the PMPRB's CPI Guidelines and usually to an even greater extent by provincial policies.

Third, in a period of fluctuating exchange rates, there will be greater uncertainty for pricing and marketing purposes. Patentees cannot predict or control this factor.

Fourth, it is unreasonable to hold a Canadian manufacturer accountable for a decision to remove a product from the market in another country.

Finally, we note that the draft Guidelines do not work both ways. They would require price reductions, but never allow price increases if supported by changes in exchange rates, price increases in other countries or the introduction of the drug at a higher price in another country. This illustrates the inherent unfairness of the proposed provisions.

Recommendation:

Rx&D recommends that the Board remove these provisions and not require patentees to lower prices in the circumstances described. The CPI Guideline, provincial policies and market forces provide adequate protection against excessive prices in these circumstances. If the Board considers that some mechanism is required, we are prepared to work with the Board to develop a more appropriate approach in today's environment.

Some General Observations:

The Notice and Comment package, the examples provided by Board Staff, and this submission illustrate the breadth and complexity of the PMPRB's policy review. They also illustrate that the complexity of the PMPRB's current Guidelines would only be multiplied if the proposed changes come into effect without substantial modification. We are very concerned that these proposals will have a harmful effect on the prescription drug market and will ultimately lead to higher prices and reduced patient choice. We are also concerned about the ability of stakeholders, including patentees, to fully digest and understand the impact of the changes in the short period of time provided and to implement them in the time proposed by the PMPRB.

One of our concerns is that these proposals reflect an intention to micro-manage the routine daily transactions in the competitive market for pharmaceuticals. In many respects they are contrary to market principles and introduce a potential to have the opposite effect of what we assume the Board seeks: These proposals as a whole create more incentives for manufacturers to resist offering discounts, free goods or other incentives in the market that serve to lower average prices and improve patient access to medicines. They discourage the offering of compassionate access programs and other benefits to government drug plans and patients.

In recent years the Board has taken the lead to amend a number of its policies in the area of over-the-counter drugs, veterinary drugs, and has proposed changes for patented generic drugs, to reduce its regulatory oversight in light of the impact of other government regulation and market forces. We believe that the Board should take a fresh approach to looking at its Guidelines for all patented drugs in the same way.

Despite all the hard work by the Board and its stakeholders, the consultation exercise has failed to achieve the necessary measure of consensus to support moving ahead at this time. We respectfully ask the Board to defer adopting its proposed changes to the Guidelines at this time and to conduct further review and analysis. We are prepared to assist the Board in this endeavour.

Attach:
Sample Explanations By Board Staff On Application Of Any Market
Sample Explanations By Board Staff On Application Of De-Linking Methodology (Dip)

SAMPLE EXPLANATIONS BY BOARD STAFF ON APPLICATION OF DE-LINKING METHODOLOGY (DIP)

Assumptions for all examples - HIPC $15.00 and TCC $12.00, therefore intro MNE price $12.00, constant yearly CPI of 2%

(1) De-linking - example one - a benefit in one market - no excessive pricing

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$10,00	$10,00		$10,00	$12,00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10,00	$6,00		$8,00	$10,20	N-ATP less than N-MNE, no review at the level of any market
year 3	$10,00	$6,00		$8,00	$8,16	N-ATP less than N-MNE, no review at the level of any market
year 4	$10,20	$10,00		$10,10	$8,16	N-ATP exceeds N-MNE, triggers investigation criteria Patentee provides evidence to meet de-linking conditions in Pharmacy class Previous highest ATP for Pharmacy is $10.00 ATP in Pharmacy class in year 4 not excessive Review at the level of any market Price in Wholesaler class rose by no more than CPI, no excessive pricing
year 5	$10,40	$10,00		$10,20	$10,30	N-ATP less than N-MNE, no review at the level of any market

(2) De-linking - example two - a benefit in one market - excessive pricing

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$9,00	$10,00		$9,50	$12,00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$9,00	$10,00		$9,50	$9,69	N-ATP less than N-MNE, no review at level of any market
year 3	$8,00	$10,00		$9,00	$9,69	N-ATP less than N-MNE, no review at level of any market
year 4	$9,50	$10,00		$9,75	$9,18	N-ATP exceeds N-MNE, triggers investigation criteria Patentee provides evidence to meet de-linking conditions in Wholesaler class Previous highest ATP for Wholesaler is $9.00 ATP of $9.50 in Wholesaler class excessive

(3) De-linking - example three - two benefits in the same market

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$10,00	$10,00	$10,00	$10,00	$12,00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10,00	$10,00	$8,00	$9,33	$10,20	N-ATP less than N-MNE, no review at the level of any market
year 3	$10,20	$10,20	$7,50	$9,30	$9,52	N-ATP less than N-MNE, no review at the level of any market
year 4	$10,20	$10,40	$9,50	$10,03	$9,49	N-ATP exceeds N-MNE, triggers investigation criteria Two benefits were introduced, one in year 2 and one in year 3 Patentee provides evidence to meet de-linking conditions for year 2 benefit in Hospital - impact of loss of this benefit results in previous highest ATP of $9.50 in Hospital class - ATP in Hospital not excessive Review at the level of the any market Prices in Wholesaler and Pharmacy rose by no more than CPI, no excessive pricing
year 5	$10,20	$10,40	$9,50	$10,03	$10,23	N-ATP less than N-MNE, no review at the level of any market

(4) De-linking - example four - variable uptake of one benefit in one market

year 1	$10,00	$10,00	$10,00	$10,00	$12,00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10,00	$10,00	$9,00	$9,67	$10,20	N-ATP less than N-MNE, no review at the level of any market
year 3	$10,00	$10,00	$8,00	$9,33	$9,86	N-ATP less than N-MNE, no review at the level of any market
yeaer 4	$10,00	$10,00	$7,00	$9,00	$9,52	N-ATP less than N-MNE, no review at the level of any market
year 5	$10,00	$10,00	$8,50	$9,50	$9,18	N-ATP exceeds N-MNE, triggers investigation criteria Patentee provides evidence that fluctuation in Hospital class due variable uptake of a bulk offer Previous highest ATP in Hospital class is $10.00, no excessive pricing Review at the level of any market Prices in Wholesale and Pharmacy did not increase, no excessive pricing
year 6	$10,20	$10,20	$8,50	$9,63	$9,69	N-ATP less than N-MNE, no review at the level of any market

(5a) De-linking example five - a benefit in one customer class in introductory period

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$10,00	$10,00	$7,00	$9,00	$12,00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10,00	$10,00	$10,00	$10,00	$9,18	N-ATP exceeds N-MNE, triggers investigation criteria Patentee provides evidence that hospital knew that it was receiving a benefit Review of other non-discounted markets, previous highest ATP for Hospital would be $10.00 as this price in the two other markets was not excessive ATP in Hospital in year 2 is not excessive
year 3	$10,20	$10,20	$10,10	$10,17	$10,20	N-ATP less than N-MNE, no review at the level of any market

(5b) De-linking example five - a benefit in one customer class in introductory period

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$7,00			$7,00	$12,00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10,00			$10,00	$7,14	N-ATP exceeds N-MNE, triggers investigation criteria Patentee provides evidence in terms of a contract that shows the price prior to the benefit and that the non-discounted price was $10.00 ATP in Wholesaler in year 2 is not excessive
year 3	$10,00			$10,00	$10,20	N-ATP less than N-MNE, no review at the level of any market

(5c) De-linking example five - a benefit in one customer class in introductory period

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$7,00			$7,00	$12,00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10,00			$10,00	$7,14	N-ATP exceeds N-MNE, triggers investigation criteria Patentee indicates that the price in year 1 included a benefit - a review of the patentee's first day of sale shows an ATP of $10.00 ATP in Wholesaler in year 2 is not excessive

(6) New customer class added post-intro - no benefits in that class

	Wholesaler	Pharmacy	Hospital	Nat'l ATP (N-ATP)	Nat'l MNE price (N-MNE)	Notes
year 1	$10,00	$10,00		$10,00	$12,00	N-ATP less than N-MNE, no class of customer higher than N-MNE
year 2	$10,00	$10,00	$8,00	$9,33	$10,20	N-ATP is less than N-MNE, no review at the level of any market
year 3	$10,00	$10,00	$9,00	$9,67	$9,52	N-ATP exceeds N-MNE, triggers investigation criteria Review at the level of any market Prices in Wholesale and Pharmacy did not increase, no excessive pricing ATP in Hospital in year 3 excessive as price increase more than CPI