SUBMISSION TO THE

PATENTED MEDICINE PRICES REVIEW BOARD

ON ITS DISCUSSION PAPER OF JANUARY 31, 2008

"Options for Possible Changes to the
Patented Medicines Regulations, 1994
and the Excessive Price Guidelines"

Response from:

Canada's Research-Based Pharmaceutical Companies

March 3, 2008

Introduction

The Patented Medicine Prices Review Board's (PMPRB) Discussion Paper of January 31, 2008 represents the latest step in public consultations on the Excessive Price Guidelines, which began in May 2006, and on the implications of the Federal Court decision in *LEO Pharma* in March 2007. Canada's Research-Based Pharmaceutical Companies (Rx&D) and its member companies have been actively engaged in these consultations throughout. We have taken part in every forum and meeting; this is our third written submission; our members have participated in meetings and made formal submissions; we are taking part in the working groups; and we have been meeting frequently with Board Staff for several months.

Despite the extensive submissions we have made to date, the proposals and options identified by the Board in the Discussion Paper, with limited exceptions, do not address or take into account the submissions and recommendations by Rx&D and individual patent-holding manufacturers. As the only stakeholders subject to the Board's regulatory oversight, pharmaceutical patentees are the principal stakeholders and are in the best position to assess the impact of the Board's proposals on the pharmaceutical market. We encourage the Board to take into account and address our suggestions in this paper and in our previous submissions.

We understand, and share, the Board's desire to conclude its review of the Guidelines this year. We also believe that any changes the Board may make may have a profound impact on the pharmaceutical market in Canada and that it is essential that the Board ensure that each change is consistent with the *Patent Act* and the Board's mandate; there is a strong and well-supported case for the change; there is a solid analysis of the desired and likely impact; and, to the greatest extent possible, there is a consensus among stakeholders on the need for and substance of the change. On this basis, more work is required on the proposals and options set out in the Discussion Paper.

We remain concerned about the silo approach to policy-making. The issues under consideration by the Board are running along parallel tracks even though there are significant linkages among them. The silo approach makes it difficult to assess and comment on the proposals and options in the Discussion Paper.

It is also necessary to ensure adequate time for consultation. The Discussion Paper has presented complex proposals and options, in some cases for the first time. Our members considered that the time for response, only 21 business days, was inadequate. In response to our request for an extension, the Executive Director of the Board advised:

> ... the Board is unable to grant an extension due to its planned Board meeting to discuss stakeholder submissions on March 6-7, 2008. However, given that the Board's focus will only be on the high-level merits of the options and not on the technical details, I encourage Rx&D to make its preliminary views known by the March 3, 2008 deadline and then follow this with its more detailed comments. I would also like to

> reassure you that there will be opportunities for further input and comment as the overall review progresses through to the Fall.

This paper sets out a high level response to the proposals and options in the Discussion Paper and we look forward to further opportunities to comment in future.

"Any Market" Price Review

Throughout the history of the PMPRB, its guidelines have provided for the ongoing monitoring and review of prices on the basis of an Average Price in Canada. Although the guidelines are based on a national Average Price, the Board always has the capacity to review prices "in any market in Canada" as provided by section 83 of the Act.

This approach has worked. The evidence presented in the May 2006 Discussion Guide showed that prices for all drugs by class of customer, and by province and territory, were overwhelmingly within the range of 5% of the national Maximum Non-Excessive (MNE) price or lower.

A review of the submissions received by the Board on this subject shows that most stakeholders are opposed to moving away from the national market approach. In its May 2007 *Stakeholder Communiqué*, the Board said:

> Through the Board's consultations, stakeholders expressed the view that, ***if*** reviews are conducted at the level of any market, ***they should be undertaken where warranted, on a case-by-case basis***. The Board agrees with this approach …(emphasis added)

The latest Discussion Paper repeats this conclusion which on its face reflects the current practice.

The detailed proposal in the Discussion Paper is not consistent with a "case-by-case" approach. On the contrary, it would impose a *de facto* full submarket price review.

The proposal would specifically apply a submarket price review for all new patented drugs and for those subject to Voluntary Compliance Undertakings and Board Orders. This change would appear to signal a new policy objective of the Board that prices in all submarkets should not exceed the national MNE price. If so, such a change would be premature. Factors touching on the appropriate definition of MNE price and the calculation of the Average Price are under study in other areas of the Board policy reviews, e.g. *LEO Pharma*.

In addition, the submarket price review would apply whenever the national Average Price appears to exceed the MNE price. As there is always a risk of inadvertent pricing slightly above the MNE under the current methodology, even if there is no change in the price, (e.g., as a result of sales mix shifts), patentees will need to monitor their compliance in all

submarkets on an ongoing basis in order to avoid the risk of enforcement action by the Board.

The true effect of this proposal then is to move from the current one-market Average Price in Canada model to a 56-submarket model.

There is no analysis of the impact of this change on incentives to offer discounts or rebates, given the current CPI-Adjusted Methodology. For example, many "price increases" as that term is used by the Board are not increases in the price at all, but rather changes in the calculated net price due to changes in the value of discounts offered or shifts in the mix of sales. Will the change to a submarket price review change the incentives for patentees to offer discounts and rebates? How will specific markets, such as hospitals, be affected?

There is no analysis of the implications of this proposal on the workload of the Board and of manufacturers. Reviewing prices in 56 markets rather than one will clearly increase the Board's workload and add to the regulatory burden for patentees. More specifically, it will increase the burden on patentees by requiring them to ensure that prices remain within the calculated guideline maximums in 56 markets rather than one market. Such a change is inconsistent with federal policy objectives to reduce the regulatory burden by 20%.

The Board has not provided the analysis and evidence to support the need for this proposal. It has not shared its analysis of the few cases where prices in submarkets exceeded the MNE prices by a significant amount nor has it explained if and why it considers its current methodologies and practices to be inadequate.

Re-setting the MNE Price

The current criteria for re-setting the MNE price and the practice of re-setting the price when warranted on a case-by-case basis continue to be appropriate. We are concerned that the new specific criteria proposed by the Board may limit the circumstances under which it may be prepared to re-set the price in some cases but expand them in other cases in an unpredictable way.

We are concerned about the implications for the Special Access Program (SAP). The current guidelines, at least in theory, provide that a price may be re-set when the drug receives its Notice of Compliance but the proposed criteria to re-set the MNE price in these circumstances will create an extremely high threshold. The effect of this proposal then would be to discourage manufacturers from supplying drugs under SAP at prices lower than the price that they would intend to sell at when the drug receives its Notice of Compliance. Uncertainty about the PMPRB's pricing policies may discourage manufacturers from supplying drugs to Canadians under SAP at all.

We are also concerned about the proposal to re-set the MNE price based on new "scientific information/evidence." The proposed circumstances are vague and could open the door to frequent debates whenever new scientific studies are published. They create uncertainty and raise the potential for price changes in Canada that are not in line with pricing in other countries. We are concerned by any proposal that will create a process or a result that will put the Canadian market out of step with other major countries and add to the barriers to bringing products to market in Canada.

It is also unclear why the Board needs to expand its activities in this way given its excessive price mandate. There are existing mechanisms in other bodies to ensure that drug plans are able to adjust their coverage and reimbursement criteria based on new scientific evidence. Such a re-review by the Board would be redundant.

The Board has not provided an analysis of the extent to which it has re-set MNE prices in the past under the current criteria nor provided an analysis of what the impact of its proposals would be. Several of the proposed criteria are not fully developed, e.g., "costs of making and marketing" and the Progressive Licensing Framework. For this reason alone, it would not be appropriate to adopt the proposals on "re-setting the MNE price" at this time.

FCC Decision – *LEO Pharma*

In Rx&D's view, the Federal Court decision in the *LEO Pharma* case does not require the Board to make the policy change announced in the April 2007 NEWSletter. Last summer, we provided the Board with the legal opinion we received that supports that conclusion. We understand that the Board has received different legal advice, but it has not shared that advice with us. To date, we have not reached common ground on the need for changes to address the implications of the *LEO Pharma* decision. Rx&D remains willing to meet with PMPRB counsel to discuss this issue further.

The Board has identified a range of options to address its concerns about this issue but has not yet reached any conclusions. Although we are not convinced of the need to take any action, we would not oppose changes that would maintain the previous flexibility and that would remove, or at least reduce, the disincentives in the Board's guidelines to offer compassionate release programs and other benefits that have the effect of lowering prices to patients.

There are at least two options that should be added to the list:

- The "status quo," i.e., to maintain the April 2000 policy and the flexibility to include or exclude compassionate and other special pricing programs in the Average Price. In our view, this option is available to the Board as a matter of policy, but if it considers it a regulatory matter, the Board could propose a regulatory change.
- A "de-linking" of the MNE price and the Average Price in the CPI-Adjustment Methodology. This approach would go a long way to addressing the *LEO*

Pharma concerns and provide greater clarity and certainty in the price review process in future years.

We support the option to exclude benefits to third-party payers from reporting and from calculation of the Average Price. In our view, such reporting is not required by the Regulations nor by the *LEO Pharma* decision in any event, but it will be helpful for the Board to confirm its position that such reporting is not required.

Rx&D remains concerned about those regulatory options that, in our view, are inconsistent with the *LEO Pharma* decision. They will have the effect of discouraging manufacturers from offering drugs under compassionate programs and in general from offering special pricing programs.

The guidelines options, especially option 2, move in a more positive direction in that they would help to mitigate the negative impact of the current CPI-Adjustment Methodology. However, they will not address the fundamental problem that basing the MNE price on a previous net Average Price creates a disincentive to offer lower prices or special rebates or incentives. That disincentive can only be addressed through a true "de-linking" of the Average Price and MNE price.

"De-linking" the Average Price and MNE price refers to a change in the CPI-Adjustment Methodology whereby MNE prices in subsequent years would be based on the MNE price in the introductory year, adjusted for changes in the Consumer Price Index, rather than the net Average Price, as is the case today.

Manufacturers have learned to work with the current system for close to 15 years, but it is less than ideal. The lengthy discussions on the implications of the *LEO Pharma* decision illustrate that tinkering with the current system may only create additional problems and potential market distortions. In our view, it would be appropriate to revisit the CPI-Adjustment Methodology and to look seriously at the concept of de-linking the MNE price and the Average Price. Such an approach would be consistent with the *Patent Act* and could be used as a basis for establishing a model that is much simpler and less cumbersome both for the Board and for patentees.

Moving Forward

Rx&D has demonstrated its good faith by fully cooperating with the Board in its consultations on these initiatives. We appreciate the opportunities to share our views but are disappointed that the Board has not addressed our submissions in most of the proposals and options presented in the Discussion Paper.

We have proposed some concrete steps to move these issues forward and look forward to a positive response from the Board.