Discussion Paper-*Options for Possible Changes*

Stakeholder Feedback on the January 2008 Discussion Paper

On January 31, 2008, the PMPRB released a Discussion Paper entitled *Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines*. The Board received 43 submissions on the Discussion Paper.

> The PMPRB Discussion Paper – *Options for Possible Changes* to the *Patented Medicines Regulations, 1994 and the Excessive Price Guidelines* and the submissions received can be found on our Web site under Consultations; Consultations on the Board's Excessive Price Guidelines.

At the Board meeting on March 6-7, 2008, considerable discussion was held on the submissions received on the Discussion Paper. The Board values the input of its stakeholders and was pleased to receive a wealth of responses from a wide range of organizations and individuals. The following is a summary of the major proposals and options found in the Discussion Paper, as well as stakeholder feedback and preliminary responses from the Board.

Any Market Price Review

Proposal: The Board was seeking comments on four proposed circumstances when a price review at the level of "any market" (i.e., class of customer or province/territory) would be conducted.

Stakeholder Feedback: In general, representatives of the pharmaceutical industry were opposed to the proposed circumstances for any market price review, believing the approach to be unwarranted and unnecessary. On the other hand, most consumers, federal/provincial/territorial (FPT) governments and other respondents felt the PMPRB should exercise its authority to undertake price review in any market in order to limit significant price disparities.

Board Response: In principle, the Board agrees that price reviews at the level of any market should be conducted as part of its mandate to ensure that the prices charged by patentees for patented medicines sold in Canada are not excessive, thereby protecting consumers and contributing to Canadian health care.

The Board believes the proposed circumstances for any market price review are reasonable, will not pose an undue burden on patentees or Board Staff, and will contribute positively to the Canadian health care system by ensuring that individual customer classes and jurisdictions do not pay excessive prices. The Board will be giving further consideration to the specific methodology for conducting price reviews at the level of any market.

Re-Setting the MNE Price

Proposal: The Board proposed three circumstances when it would be appropriate to consider re-setting the maximum non-excessive (MNE) price on a case-by-case basis (i.e., based on: the cost of "making" and "marketing" a drug product, new scientific information or evidence, or when the medicine is sold in too few countries when introduced in Canada).

Stakeholder Feedback: In general, respondents from the pharmaceutical industry did not support the proposed circumstances for re-setting the MNE price, stating the proposals would limit the circumstances in which a price could be re-set and increase uncertainty in prices. Other respondents were more supportive of these provisions, but all stakeholders felt that clear definitions were needed for the cost of "making" and "marketing" and that "triggers" for when prices would be re-set based on new scientific information or evidence, needed to be identified. The vast majority of respondents were opposed to lowering the number of countries, or changing the number of years, before an "interim" price is re-set.

Board Response: The Board's intention for the proposals in the Discussion Paper was not to limit the circumstances for possible re-setting the MNE price, but to elaborate on likely situations where re-setting may be considered. By incorporating the proposed circumstances into the Guidelines, Board Staff would have more latitude to address the re-setting of a price, without having to bring the matter before the Board in the context of a hearing (which is the current situation). Other case-by-case circumstances could also arise in which patentees may argue that the price should be re-set, and would be open to consideration by the Board in a hearing.

The Board agrees with respondents that clear definitions are needed for the cost of "making" and "marketing" and that clearly identified triggers are needed for MNE price re-setting based on new scientific information or evidence. The Board will therefore defer its final decision on the circumstances for re-setting, pending the report of the expert consultant that has been contracted to prepare a paper on activities to be included or excluded from the definition of making and marketing, which will be reviewed by the Working Group on Making and Marketing (ss. 85(2) of the *Patent Act*). Triggers for re-setting the MNE price based on new scientific information or evidence will be developed by Board Staff in consultation with scientific experts, as needed. The current number of countries and number of years before an "interim" price is re-set will be retained.

Options to Address Issues Arising from the Federal Court of Canada Decision in LEO Pharma

Regulatory Changes

Options: The Board put forward a range of possible regulatory change options to mitigate concerns arising from the Federal Court of Canada decision. The options consisted of a number of possible regulatory changes designed to modify, and/or clarify, what information patentees would need to report as part of their regulatory obligations related to net average prices, as well as an option that would permit the Board to exclude certain in under limited circumstances.

Stakeholder Feedback: Overall, the majority of the feedback focused on the option to exempt patentees from the requirement to report benefits (payments) provided to third-party payers (i.e., Option 2), as well as the option permitting the Board to disallow benefits in limited circumstances (i.e., Option 6).

Respondents from the pharmaceutical industry supported Option 2, which was also supported by some respondents representing provincial drug benefit plans. Other respondents did not support this option, emphasizing that all benefits should be taken into consideration in the determination of the net average price. Representatives of the pharmaceutical industry opposed Option 6, although it was supported by a number of other non-industry representatives that chose to respond.

Board Response: The Board does not take the option of regulatory amendments lightly, and will be giving further consideration to proposed amendments over the next few weeks.

Guidelines Changes Relating to CPI

Options: The Board put forward two options for possible Guidelines changes affecting the CPI-Adjustment Methodology for determining the MNE price.

Stakeholder Feedback: In general, respondents from the pharmaceutical industry favored the option establishing the MNE price by using the greater of the introductory MNE price and the CPI-adjustment methodology, using the highest previous non-excessive average price (i.e., Option 2), but did not feel the option sufficiently addressed the issues at hand. The majority of respondents from the pharmaceutical industry requested that the Board consider an alternative option, where, if the average actual introductory price was below the introductory MNE price, the MNE price at introduction would increase by CPI on an annual basis and at any time patentees could increase their average price to this level. Other respondents supported both options put forward in the Discussion Paper, but only if there was a constraint placed on maximum single-year price increases.

Board Response: The Board believes that, in principle, both options in the Discussion Paper have merit, but shares the concerns of many respondents regarding the potential impact of a single year price increase, and the complexity and inter-connectedness of these options with other issues (e.g., any market price review, re-setting the MNE). The Board will therefore defer its decision on these Guidelines options, until other aspects of the Guidelines Review exercise are further advanced and all options can be considered in a more comprehensive manner.

Additional Updates from the Board Meeting on March 6-7, 2008

The Working Groups on Therapeutic Improvement and on the International Therapeutic Class Comparison presented their preliminary findings to the Board on March 6, 2008, and submitted their reports on April 4, 2008.

The Board would like to thank the members of both Working Groups for their considerable efforts.

> The final reports of the Working Groups on Therapeutic Improvement and International Therapeutic Class Comparison are posted on our Web site under Consultations; Consultations on the Board's Excessive Price Guidelines as are the Terms of Reference for all Working Groups.

The Board also endorsed the Terms of Reference and membership of the Working Group on Price Tests, which held its first meeting on April 9, 2008.

Next Steps

The Board remains committed to its goal to have the Guidelines Review exercise completed by the fall of 2008. To this end it expects to issue a *Stakeholder Communiqué* later this spring on its decisions with regard to some outstanding issues, and to further consult with stakeholders during the summer on a comprehensive package of proposed changes to the Guidelines. If the Board decides to pursue regulatory changes, further information will be included in the spring *Communiqué*.

The Board looks forward to the continued support and input of all its stakeholders in this review exercise. ■