Patented Medicine Prices Review Board

Stakeholder Communiqué

May 31, 2007

– *Review of the Board's Excessive Price Guidelines*

The Board wishes to thank all stakeholders who provided written submissions in response to the May 2006 Discussion Guide and those who participated in the November consultations held across Canada. The Board appreciates the effort and time that went into these activities. The resulting comments were thoughtful and valuable.

The Board has given careful consideration to all of the views and comments it has received. The purpose of this letter is to communicate the Board's preliminary response to the issues and views expressed regarding the Excessive Price Guidelines. Additional work will be required to develop possible options, and the Board will provide stakeholders with opportunities for further input as this work progresses.

Principles

Over the years, some stakeholders have linked various principles to the Board's mandate, such as, lowest reasonable price, price stability and price predictability, to name a few. The Board is cognisant that the Government's objective in creating the PMPRB was to ensure the additional patent protection provided to pharmaceutical patentees stemming from changes in the *Patent Act* (Act) did not translate into excessive prices. In keeping with this objective, 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 Board intends to include language to this effect in the preamble to the Guidelines.

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Categories

The Board heard a variety of views on this subject ranging from abandoning all categories to adopting models used in other countries. The Board believes that some assessment of therapeutic value is needed and work on options for possible revisions to the current approach is appropriate. To this end, the Board will establish a Working Group whose mandate will be to examine the possibility of developing definitions or parameters relating to "breakthrough/substantial improvement", "moderate improvement" and "little or no improvement," along with supporting evidence requirements.

International Therapeutic Class Comparison

Under the second part of paragraph 85(1)(c) of the Act, the Board shall take into consideration the prices at which other medicines in the same therapeutic class have been sold in countries other than Canada. The Board recognizes that this is not a factor that is described in its Guidelines. As a first step, the Board will establish a small group of experts to develop a methodology for identifying appropriate therapeutically comparable medicines in comparator countries. The focus of the mandate for this group of experts will be based on scientific and clinical considerations only and will not include work on possible price tests nor when or how this factor may be incorporated in price tests.

Price Tests

As a result of the decision to establish the above Working Groups, the Board is reserving comment on price tests in general and their use.

Costs of Making and Marketing

Pursuant to subsection 85(2) of the Act, where after taking into consideration the factors referred to in subsection 85(1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may consider the costs of making and marketing a patented medicine in determining whether or not its price is excessive. While, to date, the Board has not had to give consideration to subsection 85(2) to make a determination of excessive pricing, it recognizes this situation could arise. As a result, the Board will be considering specific circumstances where it may be appropriate to consider these costs. It will also be seeking input from experts and stakeholders on how making and marketing should be defined, what type of cost evidence would be needed, as well as what would be considered appropriate sources of such evidence.

Price Increases

In the interest of the completeness of its review of its Guidelines, the Board has also undertaken an assessment of its current CPI methodology. The Board considers the current methodology to still be sound and notes that it was agreed to by stakeholders as an appropriate compromise relative to other

possible methodologies. However, the methodology can, for example, result in rare circumstances where the MNE price calculated for the year under review is less than or equal to the average transaction price (ATP) of the previous year which was within the Guidelines. The Board does not believe this was the intent of the methodology. The Board will be drafting language to permit some flexibility in applying the existing CPI methodology for comment by stakeholders.

Adjusting the Benchmark Price (Re-benching)

The Board has deemed 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, namely:

(1) When a drug product is sold as an Investigational New Drug (IND) or under the Special Access Program (SAP), it may be appropriate to adjust the benchmark price when the drug is granted a Notice of Compliance (NOC).

(2) When the pivotal introductory price test for a drug product is the median International Price Comparison (IPC) (i.e., for Cat. 2 drug products, or when a Therapeutic Class Comparison (TCC) test is not appropriate) and the drug is sold in less than 5 countries it may be appropriate to re-bench the MNE price when the drug is sold in five countries or after 3 years, whichever comes first.

Any Market

The Act confers on the PMPRB the right and responsibility to ensure that patented medicine prices are not excessive in "any market" or in the "relevant market" in Canada. The *Patented Medicines Regulations, 1994*, require patentees to file pricing information by class of customer (i.e., hospitals, pharmacies, wholesalers and others) as well as by province and territory. 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 and will be identifying circumstances where it may be appropriate to review prices in any market.

Next Steps

To facilitate the process of further considering possible changes to the Guidelines, the Board will be holding bilateral meetings with stakeholder groups to obtain feedback.

The Board is committed to carrying out its mandate in a manner that is transparent and predictable to all stakeholders. The overall role of the Guidelines is to provide clear guidance to Board Staff and patentees with respect to the approach to be used in conducting price reviews, and to promote voluntary compliance by patentees in setting non-excessive prices for patented medicines sold in Canada.

Once again, the Board thanks all stakeholders that have provided comments to date. As the Board continues the review of its Guidelines, stakeholders will have opportunities for further input.