Boehringer Ingelheim (Canada) Ltd/Ltée - Burlington, Ontario

VIA TELEFAX

Boehringer Ingelheim (Canada) Ltd/Ltée

Corporate Administration
President and Chief Executive Officer

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Ms. Sylvie Dupont
Secretary of the Board
Patented Medicines Prices Review Board
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Dear Ms. Dupont:

As a patentee of a number of innovative pharmaceuticals, Boehringer Ingelheim (Canada) Ltd. (BICL) would like to take this opportunity to comment on the Patented Medicine Prices Review Board's (PMPRB) recently released *Discussion Guide for the Consultations on the Board's Excessive Price Guidelines*. It is vital that input from all stakeholders be considered prior to commencing changes to the Price Guidelines.

In order to evaluate the Board's Excessive Pricing Guidelines within the context of the discussion guide, we refer to the mandate of the PMPRB as well as the Board's attempts to expand that mandate over the last few years:

Regulatory – To protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive

Reporting – To contribute to informed decisions and policy making by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees

This mandate is a result of powers granted by the *Patent Act* which allows the PMPRB to ensure that patentees do not abuse the rights afforded as a result of product patents. BICL believes that the jurisdiction of the PMPRB is only within this scope.

In the years since the passage of Bill C-91, the Board has attempted to extend its mandate beyond that which Parliament originally intended. BICL believes that any discussion with regards to the Excessive Price Guidelines must be made within the context of what we believe to be the approved mandate of the Board.

Based on the 2005 decision in the Nicoderm case, the Federal Court ruled that the PMPRB had no jurisdiction in the patent application (pending) period. Notwithstanding this ruling, the Board continues to claim jurisdiction of the patent pending period, assessed retroactively once the patent has been issued. It is BICL's belief that the Board's jurisdiction should only apply to the period after the issuance of the patent.

Based on the Federal Court of Appeal's decision in ICN Pharmaceuticals Inc. vs. Canada, the Board is also attempting to expand its mandate with regards to the issue of "patent pertaining," citing that the nexus between the patent and the medicine can be one of the merest slender thread. The net result is that the Board can claim jurisdiction over products that have no intellectual property protection and may even face generic competition – a situation that is clearly beyond the mandate of PMPRB that was anticipated by Parliament. BICL believes that only patents listed on the Health Canada Patent Register (i.e., those that provide intellectual property protection) should be subject to the mandate of the Board.

In response to the current consultation, following are BICL's responses to the issues as posed:

Issue 1

Is the current approach to the categorization of new patented medicines appropriate?

The existing categorization of medication is restrictive and cumbersome. The current classification system does not recognize incremental advances for medicines classified as Category 1 or Category 3, or the value of innovation for Category 2 drugs. The PMPRB should recognize that the innovative value of new products is already established by Health Canada in the approval process and this should be taken into consideration when determining an appropriate price.

We believe that a medication does not have to be a new active substance (NAS) to provide additional benefits as compared to the reference medicine. For example, a novel formulation may improve drug delivery resulting in an increase in efficacy or a significant increase in safety and/or tolerability. Under the current classification scheme, these types of products are classified as Category 1 drugs and must be price similarly to the original formulation.

With Category 3, the requirement for comparisons to agents within the 4th level ATC classification can result in comparisons being made to older products that are not valid comparators as they may have decreased clinical value and may no longer represent the standard of care in clinical practice.

The value of breakthrough drugs (i.e., Category 2) is generally not well recognized by the PMPRB. A number of new products introduced in 2005 were considered by regulatory authorities and clinicians as groundbreaking therapies, however, of the 35 new patented drugs (distinct chemical entities) introduced and reviewed by the PMPRB in 2005, only one was recognized as a breakthrough product by the PMPRB.

Issue 2

Is the current approach used to review the introductory prices of new medicines appropriate?

The current pricing tests are restrictive and do not always accurately capture the incremental value of a product. The PMPRB appears to be of the opinion that in many instances the introductory price of Category

3 medicines exceed that of Category 2 medicines. The discussion guide states that 65% of Category 3 drugs introduced in 2004 would have been able to price higher than the international median price as per the International Price Comparison (IPC) should they have chosen to price according to the Therapeutic Class Comparison (TCC). The Board must recognize that market forces regulate the price of new products independent of PMPRB rules and price tests. Drugs are priced to be competitive in the Canadian environment, which is why they may not be introduced at the 'maximum allowable price'. Finally, since Category 3 medications can be priced equally to the price of Category 2 medications it is evident that the price tests do not accurately reflect the value of category 2 medicines.

In terms of determining the appropriate comparator medicines, the following points should be considered. A comparator medicine should be first identified as one where the main indication is the same as that of the medicine being evaluated. Furthermore, clinical evidence and practice should be considered. For example, comparators could be identified in treatment guidelines or via comparative clinical trials. The definition should not be based on the ATC classification but should be more open and consistently encompass other molecules which are used in the real world setting.

Issue 3

Should the Board's Guidelines address the direction in the *Patent Act* to consider "any market"?

BICL strongly believes that that current system of a national average transaction price (ATP) is appropriate. The pharmaceutical marketplace as it exists today is able to provide different levels of pricing to certain parties (e.g., hospitals) based on volume purchases and contracts. There is no evidence that lower prices are provided to some customers at the expense of others. In fact, most Canadian customers pay prices that are 5% below the maximum non-excessive (MNE) price. It is our opinion that changing to a regional ATP could result in the elimination of pricing agreements, thereby putting those institutions and regions benefiting from such arrangements in a position of disadvantage. Again,

this is an example where market forces help ensure competitive prices in the marketplace as opposed to PMPRB regulations.

In addition, a system of regional or customer-based ATPs would increase the administrative burden on both the PMPRB and manufacturers. BICL does support the further investigation of an ATP at a more detailed level should there be evidence that a price is excessive in relation to the Guidelines, however the presence of simple variability between different markets should not be sufficient to warrant the initiation of an investigation.

Finally, it is important to consider that patent legislation in Canada is federal in nature. The rights and responsibilities afforded by this legislation are national in scope. It is impossible to realize value from this legislation if pricing is examined at numerous sublevels.

Since the inception of the Guidelines in 1988, the Board has expanded its mandate and increased the number of restrictive policies in order to ensure that Canadian prices are not excessive. It is our belief that notwithstanding the presence of the Price Guidelines, the prices of Canadian medicines are regulated by market forces. We believe that the PMPRB should consider a system that is less 'rules based' in determining whether a price is appropriate and should instead focus on ensuring that prices are not excessive as per their mandate. Finally, it is important to consider that the original purpose of the *Patent Act* and subsequently the Guidelines was to ensure a balance between consumer protection (prevention of excessive pricing) and the recognition of the value of pharmaceuticals (patent protection). Any changes made to the Excessive Price Guidelines must ensure that a balance is maintained between these two considerations.

Sincerely,

BOEHRINGER INGELHEIM (CANADA) LTD.

Ian R. Mills