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

Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
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Corporate Administration

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Dear Ms. Dupont:

Re: Price Increases for Patented Medicines: Discussion Paper

Boehringer Ingelheim (Canada) Ltd. (BICL) has a number of innovative medications which fall under the auspices of the Patented Medicine Prices Review Board. As such, the following is our response to the Board's invitation to all stakeholders to comment on the discussion paper it has issued on price increases for patented medicines.

The PMPRB indicated that all relevant questions be considered within the context of the Board's mandate. Because a patent for a medication affords a degree of power to a patentee, it is the role of the PMPRB to ensure that a patentee is not taking untoward liberties within this context. It is not within the mandate of the PMPRB to implement many of the suggestions in the proposed framework and discussion questions. Further discussion on the frameworks and questions can be found below.

In their discussion paper, the Board highlighted the fact that during 2004, several manufacturers increased the prices of their patented products, and cite these increases as rationale for initiating dialogue with stakeholders. Within this context, the Board has not provided any evidence that these increases are inappropriate or contrary to established guidelines. The PMPRB has also expressed concern that Canada may be seeing a change in the price stability of patented medicines. We believe that it is premature to make such a blanket statement based on data from a one-year period. Furthermore, from an economic perspective, price stability occurs when prices keep up with inflation, not when they consistently fall behind as has been

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the case with patented medicines in Canada. The fact that prices (on average) did not increase for several years was the result of manufacturers responding to market conditions at that time. The reality is that over that period, prices of some medications increased, others decreased, and many remained unchanged. The overall effect is that in real terms, prices have actually declined over the last decade while the cumulative increase in CPI has risen by 21.6%. The fact that many more patentees are now considering prices increases, speaks to a change in the market conditions as opposed to a move to excessive pricing.

Although BICL welcomes the opportunity to participate in this dialogue, we would like to acknowledge that there is little indication that a discussion on price increase guidelines is warranted at this time as there is little evidence to show that Canada is experiencing a change in the price stability of patented medicines.

Since the inception of the PMPRB in 1987, the concept of balance between industrial benefits and consumer protection has been emphasized by Parliament. This has been evident in the process and amendments made to the Patent Act in both 1987 and 1994. This concept has also been recognized by the PMPRB. In its 2005-2006 *Reports and Plans and Priorities* the Board acknowledges the importance of the balance established by Parliament:

> *"The PMPRB represents the strategic component of the federal government's policy to balance consumer protection and affordable health care with the trade and industrial development objectives of pharmaceutical patent legislation".*

The discussion paper on price increases does not convey the importance of maintaining a balance between these two objectives and only talks about the concern that there may be a change in the price stability of patented medicines in Canada. It is our opinion that any discussion around making changes to the current pricing Guidelines should also include a discussion on other aspects of pharmaceutical policy including intellectual property protection, investment, as well as research and development.

Questions for Stakeholders to Consider: The Three Regulatory Frameworks

The PMPRB has proposed the following frameworks for consideration:

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1. *The current system where a patentee is able to take an automatic price increase in a given period up to a predetermined maximum. The PMPRB reviews the prices after the fact to ensure compliance to the Guidelines.*

2. *As per framework 1 but patentees would have to apply to the Board in advance to allow a review of the proposed price increase prior to implementation to ensure compliance to the guidelines. Price increases could only be implemented after approval from the Board.*

3. *As per framework 2 but patentees would be required to provide both a justification for the proposed increase and the extent of that increase. The PMPRB would then have to make a determination on both the appropriateness and the extent of the increase.*

It is BICL's opinion that the current process (framework 1) is effective, and that frameworks 2 and 3 would not add incremental benefit to any of the involved parties (consumers, patentees, and the Board). Rather, introduction of further restrictions on the price increase Guidelines could result in higher introductory prices for patented medicines given that price increases would be difficult to apply once the medicine has been introduced into the Canadian market.

We believe that Board approval of price increases to ensure compliance to the Guidelines is unwarranted. To date, there has been no evidence provided that shows that manufacturers are non-compliant with the current guidelines. Implementation of such pre approval requirements can only serve to increase the administrative burden of all parties involved. It is our understanding that the Board is currently trying to introduce an element of timeliness into its processes, the addition of price increase reviews prior to the effective date would have a detrimental effect on the workload of PMPRB staff. In addition, there are currently no guarantees that price increase proposals submitted by manufacturers would be approved within an appropriate timeframe.

In our opinion the concept of justification of price increases is already part of the Guidelines. All price increases for patented medication are tied to the Consumer Price Index (CPI) which ensures that price changes stay in line with changes in inflation. Similar to most sectors, the pharmaceutical industry experiences increases in operating costs on an annual basis. The current guidelines ensure that patentees are bound by the concept of CPI and it is the mandate of the Board to ensure that any increases taken in this context are not excessive.

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Questions for Stakeholders to Consider: Questions Raised by the Discussion Paper

1. ***Should the PMPRB Guidelines continue to allow for automatic (i.e. without prior approval) price increases?***

We believe that the current process in which price increases are reviewed after implementation is effective and based on the Patent Act, we question Board's legal authority to request prior approval of price increases. It is our understanding that the Patent Act limits the PMPRB's price review powers to the prices at which a medicine "is being" or "has been" sold and that the Board has no authority review prices at which medicines "will be" sold. The only exception to this is when a patentee voluntarily seeks pre-advisory assistance.

In their question to stakeholders, the Board makes reference to "automatic" price increases, which appears to be predicated on the assumption that patentees are automatically increasing the price of their drugs. This is not the case. Price increases occur within the context of Board guidelines and market conditions, while balancing the increased cost of doing day-to-day business.

In considering this issue, one must also address the question of efficiency and regulatory burden. While it is the Board's objective to ensure efficient and timely review of prices of new medications and price increases, the concept of prior approval only adds to the regulatory burden on PMPRB employees while providing no additional benefit to the involved stakeholders. This is relevant as the PMPRB already reviews the prices of all patented medicines biannually. Further compounding this issue is the fact that the Board is already experiencing a fair amount of regulatory strain. As of March 31, 2005 the PMPRB's website indicated that one third of the new medicines introduced in 2004 (as well as several products from prior years) had introductory prices that were still "under review".

Patentees are currently required to file their sales and price information within 30 days of the end of each six-month reporting period. There is no provision in the Regulations that requires patentees to notify the Board of price increases between reporting periods. The PMPRB is currently engaged in a separate consultation process on proposed changes to the Regulations that includes an amendment that would require patentees to notify the PMPRB of price increases 120 days in advance of their implementation. The PMPRB does not have authority to regulate prices before they have been implemented, as the Patent Act refers only to the price at which a medicine is being or has been sold, not to the price at which it will be sold in the future.

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Finally, a number of other issues are raised with respect to prior approval of price increases including the handling of confidential pricing information by the Board, the possible profit seeking activities by wholesalers should pricing information become known prior to implementation, and the loss of flexibility to competitively price products.

2. ***Are there considerations other than, or in addition to, the CPI that should be used to review price increases?***

   It is our opinion that no additional factors be considered in reviewing price increases. The Guidelines are already quite restrictive because in addition to constraints around CPI, the average selling price of a patented medicine in Canada cannot exceed the highest international price in the designated comparator countries. To add further complication, comparisons to international prices are then tied to the value of currency in each country.

   The Patent Act outlines a number of factors, including changes in CPI, which are used to determine whether the price of a medicine is excessive. The PMPRB does not have the authority to disregard factors provided in the Patent Act when considering if prices are excessive. A change to the Guidelines to no longer employ CPI as a basis for determining if price increases are excessive is beyond the PMPRB's authority and would require a change to the Patent Act.

3. ***How often should price increases occur? (e.g. every year, once every 3-5 years, only after a certain introductory period, when justified)***

   It is our position that there should be no constraints placed on either the frequency of price increase nor should it be tied to a justification. To date, the PMPRB has not provided any evidence that demonstrates that patentees are taking inappropriately frequent increases in the price of patented medicines. The Board has done an excellent job in ensuring that the prices of patented medicines are not excessive. In addition to the current limits established by the Board, there is another level of control in place that regulate the timing of price increases. Many of the provincial formularies have rules and regulations regarding the frequency of price changes which effectively limit patentees in how often they are able to adjust prices.

   Finally, the Patent Act does not address the issue of timing or frequency of price increases. Thus, the Board has no authority to impose limitations that go beyond the specific factors listed in the Act. The Board's powers are limited to determining whether the price of a particular patented medicine is excessive. If a

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given price increase is consistent with the CPI, it should not matter if it is taken all at once or in several increments or at what time of year the increases are taken.

4. ***If justification is required, what criteria should be considered?***

   It is BICL's opinion that prices justification is not required. According to PMPRB Guidelines, the only situation where the Board has the authority to request justification from a patentee is when the price of a patented medicine is found to be excessive.

5. ***Given that the CPI is established in the Patent Act as a factor to be considered by the PMPRB, do you have any comments on its appropriate application in the future guidelines?***

   To date, the CPI has been appropriately applied to pricing for existing patented medication. In addition to this use, the PMPRB should adjust the price of comparator medicines by CPI when conducting a therapeutic class comparison test. Such a change would recognize that the price of comparator drugs in the same therapeutic class developed years ago cannot serve as a credible basis for the establishment of the prices of newer drugs, notably given the difference in development cost between the two.

Conclusion

Boehringer Ingelheim (Canada) Ltd. understands and appreciates the Board's intention to comply with its mandate; however at the same time it is unclear how the questions asked in the discussion paper could even be brought into fruition given the role of the Board to regulate prices of patented medicines as defined under the Patent Act. Given this information, the Board should restrict its activities to reviewing individual cases where there is clear evidence of excessive pricing. Furthermore, the proposed frameworks 2 and 3 would hinder the role of the Board by creating additional regulatory responsibility. We express this opinion as an individual company as well as a member of the Canada's Research-Based Pharmaceutical Companies (Rx & D).

The PMPRB is of the opinion that stricter guidelines for enforcing price increases would be in line with their mandate as well as a number of ongoing and planned initiatives (e.g., the National Pharmaceutical Strategy). That being said, there are a number of issues that have not been effectively addressed in this discussion paper. The most important of these issues is the value of innovative pharmaceuticals. A cost-centric approach to managing innovation in healthcare will diminish patient outcomes

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and could result in unnecessarily increases in overall costs. In fact when looking at cost controls, ex-factory prices of medications is only one of many factors affecting the overall cost picture, the leading factor affecting total drug expenditures is medication utilization.

Finally, we believe that a discussion regarding changes in important elements of price control cannot take place without an analysis of other aspects of pharmaceutical policy including intellectual property protection, pharmaceutical investment, as well as research and development. Dialogue regarding guidelines for future price increase should not be initiated until all of these factors are taken into consideration.

Yours truly,

BOEHRINGER INGELHEIM (CANADA) LTD.

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