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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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Boehringer Ingelheim
(Canada) Ltd/Ltée

Corporate Administration

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Dear Ms. Dupont:

Boehringer Ingelheim (Canada) Ltd. (BICL) is writing to express our concern with the approach the Board has taken with respect to the interpretation of the Patent Act and its application to the Regulations, specifically the proposed amendments to the Regulations as published in January 2005.

According to the PMPRB, the Regulations need to be modernized to better reflect the information needs of the PMPRB to carry out its responsibilities under the Act. However, it appears that the several of the changes proposed by the Board are intended to facilitate a change of the current process for price changes of existing drugs as opposed to providing information to ensure patentees are in compliance with the current guidelines. It is our understanding that the current mandate of the PMPRB is two fold. First; to protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive. Second; to contribute to informed decisions and policy making by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees. It is our opinion that many of the proposed changes attempt to expand the scope of the Board while not adequately addressing its current mandate.

Notification of Proposed Price

The PMPRB has proposed that manufacturers provide the Board with the proposed price of a new medicine at least 60 days prior to the date on which the patentee first

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offers the medicine for sale. This proposal is impractical and threatens to delay patient access to new therapies.

It is often difficult to determine the date of first sale of a medication. This date is contingent on a myriad of factors, including the date of issuance of the Notice of Compliance (NOC) by Health Canada and product availability. As the exact issuance of NOC cannot be accurately predicted, such a requirement could result in a delay (up to 60 days) in the medication being made available to patients. The final price of a drug may be dependant on the market conditions at that time (e.g., competitor pricing, provincial reimbursement policies, etc.). By providing a price prior to the first sale, the flexibility of achieving a competitive price is effectively curtailed. In addition, confidentiality with regards to the final price of a drug is of paramount importance. Companies could face significant competitive disadvantage should the price of their drug be inadvertently made public prior to the launch of the drug.

Under the existing regulations, the Board requires patentees to file the first 30 days of sales (within 60 days of first sale) and again at the end of the semi annual period. The proposed change means that the pricing information for a new drug will be reviewed three times, which creates additional workload for the PMPRB. This is in direct contradiction to the Board's efforts to create a more efficient and timely system.

Notification of a Proposed Price Increase

The Board has put forward that Section 4 be modified to include notification of any proposed price increase to any customer class in Canada, 120 days prior to the effective date. Currently, each of the provincial payers, as well as other payers of drugs have different timelines with respect to notification and implementation of price changes. Introducing an additional timeline to this already arduous process would only create an environment of less flexibility in adjusting and maintaining competitive prices.

We are concerned that there is no guarantee that the PMPRB would treat this information if provided as confidential. BICL maintains that this information is highly sensitive and if it is released prior to an appropriate time could negatively impact our business. For example, profit-seeking activities (drug stockpiling) by wholesalers and pharmacies would be one consequence of releasing pricing information before the appropriate date. In addition, it is unclear what the Board will do with this information. The Board needs to clarify its intent with how it expects to utilize information regarding price increases provided by a patentee. It is reasonable that

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price changes be provided to the Board however, we suggest that this should occur that the time of increase or shortly thereafter.

Details on the Calculation of Net Price and Net Revenues

The PMPRB has also recommended that any amounts used in the calculation must be identified and reported on the appropriate form. Again it is unclear as to what the intention of the PMPRB is with respect to collecting this information. It is difficult to envision what the Board is expecting from patentees with respect to this additional information without copies of proposed new forms. The current format ensures that information provided to the Board is accurate. In the past, if clarification of calculations has been required, the Board has asked the patentee to provide further detail. The PMPRB has not provided any evidence demonstrating that the current practice is not sufficient for it to carry out its mandate in a timely and efficient manner. Finally, patentees are already required to file extensive details on pricing and any additional reporting represents a significant reporting burden to the patentee and does not improve timeliness of review on the part of the Board.

Product Monograph/Draft Monograph

The Board has proposed, under section three, for patentees to file a product monograph or a draft product monograph. Under the current system, if a patentee does not file the monograph the PMPRB must request it. There is no evidence that patentees have not provided the Board with this information when it has been request. BICL has a concern with regards to the confidentiality of the product monograph, as the Board has not provided a guarantee of confidentiality for these documents. In addition, draft product monograph may change prior to approval by Health Canada and we are concerned that any work done by the Board based on a draft may have to be redone if there is change to the monograph. This would take away from the timeliness and efficiency that the Board is trying to introduce into its practices.

Recognition of Electronic Signatures

The PMPRB has proposed to add two new sections to help facilitate the use of electronic reporting. Currently, 87% of patentees file their price and sales data electronically. A hard copy of the submission must also be filed with the PMPRB in order to have a proper signature. The new additions to the regulations would allow recognition of electronic signatures, and allow formal recognition of electronic

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submissions. As this proposal represents an efficiency in the process, Boehringer Ingelheim is in full support of this change.

Filing Requirements for Veterinary Patentees

In September 2003, the PMPRB adopted a complaints driven approach for patented veterinary products. Currently the regulations do not differentiate between filing requirements for human versus veterinary products and this needs to be differentiated. An addition to section 4(3) would rectify this situation. As this represents a clarification in the regulations, Boehringer Ingelheim supports this change.

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 several of the proposed changes would effectively contribute to that goal. We express this opinion as an individual company as well as a member of the Canada's Research-Based Pharmaceutical Companies (Rx & D). It is difficult to comment on the proposed regulations when it is unclear as to the intention of the Board with respect to the additional information it is asking patentees to provide. The PMPRB has stated that the changes to the Regulations are intended to expedite the review of pricing, however the updated Regulations do not address timeliness on the part of the PMPRB. If manufacturers provide the required information, what is the guarantee that the PMPRB will be able to complete a more thorough and timely review? This issue must be addressed within the context of the guidelines. As a concerned patentee, we request that the Board reconsider the proposed amendments to the Patent Act Regulations.

Yours truly,

BOEHRINGER INGELHEIM (CANADA) LTD.

Ian R. Mills
President & CEO