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

Ms. Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
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Boehringer Ingelheim (Canada) Ltd/Ltée

Prescription Medicine Division
Market Access & Communications

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Re: Response to PMPRB January 31, 2008 Consultation Document

Dear Ms. Dupont:

Boehringer Ingelheim Canada Limited ("BICL") wishes to respond to the Discussion Paper ("the Paper") released on January 31, 2008 by the Patented Medicine Prices Review Board ("PMPRB").

Section III Overall Guidelines Review

A. Proposed Scenarios for Consultation

Proposal - Re-setting the MNE Price (Under what circumstances should the PMPRB consider re-setting the MNE price)

1. While we applaud the PMPRB's attempt to recognize the various costs of bringing a drug to market (by adjusting the MNE), we feel it would be more appropriate to recognize that innovation when the Board initially reviews the drug – not after the fact. Re-setting the MNE would also bring a sense of unnecessary uncertainly to the marketplace, a concern of any industry. Assessing the marketing costs of a drug in our opinion clearly falls outside of the mandate of the PMPRB and therefore, should not be used in any re-setting of the MNE. We would also be interested in knowing whether using marketing costs to re-set the MNE could work in a downward setting of the price.

2. *Proposal - Availability of scientific information being non sufficient to determine its category of therapeutic improvement*

   The scenarios presented for when scientific information/evidence is limited and not sufficient to determine the categorizations should only be used when the patentee pursues a change in categorization. The amount of work required by the Board to life cycle manage all patented products would be extremely time consuming.

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3. *Proposal – How to handle situations when the median international price comparison is the pivotal test and the medicine is sold in too few countries*

BICL would support eliminating the time limit altogether and re-review the price of the product when it is sold in 3 countries, regardless of how many years from the date of first sale this may be.

Section IV Options to Address Issues Arising from the Federal Court of Canada Decision

A. Regulatory Options

Option 1- Maintain current Regulations and respect the outcome of the FCC decision (Leo Pharma case)

The requirement to respect and include all the information that came out of the FCC decision creates data collection and reporting difficulties for patentees. The Board and patentees would have to devise a way to calculate all of the benefits to determine the average transaction price. Until the Board can demonstrate how the calculations would be done, this amendment should not be considered at this time.

Option 2 – Amend the Regulations to exempt patentees from reporting benefit payments (i.e.: payments / rebates) to third party

The PMPRB does not have jurisdiction over the provinces when it comes to drug policy decisions, therefore BICL supports the proposal to exempt the reporting of benefits (many of which are confidential) to third party payors for the purpose of calculating the ATP.

Option 3 – Amending the Regulations with respect to free goods

BICL supports the recommendation to "*Amend the Regulations to exclude all free goods from the calculation of the Average Price,*" as they are not being sold so they should not be included in the price, they are stated "free".

Option 4 – Amend the Regulations to change "free services" to services (free or partially subsidized in the ATP calculation

All services, whether "free or partially subsidized," (which should be clearly defined) should not be included in the average transaction price, as it does not pertain to selling of the drug to any customer class in Canada. Services provided by a patentee may not be linked to a particular drug and therefore interpretation of inclusion is left to the patentee and may not be consistent across patentees.

Option 5 - Complete *agreement that "gifts" should be removed from regulations.*

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BICL supports this recommendation that "gifts" (which should be clearly defined) should be removed from the regulations.

Option 6 – Amend the Regulations to permit the Board to disallow any or all benefits which it determines were implemented by the patentee to reduce the liability in regard to excessive pricing in terms of the calculation of excessive revenues

Only the Board would benefit from creating a new regulation that states, "the Board would have authority which it may use only in certain limited and specific situations, to disallow the inclusion of any benefit in the calculation of the Average Price." The applicability of this provision seems very subjective and provides no clear guidance as to what benefits could be considered or not.

A. Guidelines Options

Option 2 – Amend the methodology in the Guidelines for the establishment of the MNE price by using the greater of the introductory MNE price and the CPI-methodology using the highest previous non-excessive Average Price, if the actual Average Price declines due to a new or increased benefit

As stated, this option builds on Option 1, which will allow patentees greater flexibility when introducing the product as well as serving the patients by allowing manufacturers to price the product below the MNE without the constraints of penalties should the price decrease with a new or increased benefit.

Conclusion:

After two decades of the PMPRB's existence, BICL believes that the mandate of the PMPRB has expanded beyond its original purpose. Innovation should be recognized at the beginning of a product's life cycle. We hope the Board will cease proposing policies, which we believe are intentionally designed to drive down the price of innovative and patented medicines in this country, which is not the intention of the original mandate.

Yours truly,

Derek O'Toole