BIOTECanada

April 27, 2009

Dr. Brien Benoit
Chairperson
Patented Medicine Prices Review Board
Box L40 Standard Life Centre
1400 - 333 Laurier Avenue West
Ottawa, Ontario
K1P 1C1

Dear Dr. Benoit,

On behalf of BIOTECanada member companies I would like to thank the Patented Medicine Prices Review Board (PMPRB) for the opportunity to provide comments on the *Proposed Revisions to the Compendium of Policies, Guidelines and Procedures* (the "2009 Draft Compendium") published March 25, 2009. A detailed appendix attached to this letter highlights some of the key issues identified by our members.

BIOTECanada appreciates the considerable efforts of the Board to engage Canada's biotechnology industry throughout this consultation process which began in 2005. However, over the past four years the scope of the Board's guideline review has expanded to such an extent that our members' business operations in Canada could become significantly threatened if the guidelines are implemented as proposed in the recent version. We are concerned about the proposed changes and expansion to the PMPRB mandate, which move away from the original intent of ensuring that the prices for patented medicines are not excessive toward a vague notion of "consumer protection" and increasing price control. While we agree the Board has an important role to play monitoring the prices of patented medicines sold in Canada we also believe that the Board has the responsibility to ensure that Canada maintains a business environment where innovative therapies can be introduced. The complex set of guideline revisions proposed by the Board will move Canada in the wrong direction and are inconsistent with the interests of Canadians who want access to the most modern therapeutic innovations.

The following comments address the most pressing issues facing our members.

Legal Framework – Mandate

BIOTECanada members are concerned by the Board's attempt to independently redefine and broaden its own mandate. By introducing the new statement "consistent with the interests of consumers and the Canadian health care system" the PMPRB is failing to recognize the dual role of the *Patent Act* in maintaining a balance between incentives for research and development and protection against excessive prices. Nothing in either the *Patent* Act or the *Patented Medicines Regulations* suggest a role for PMPRB other than the determination of whether or not a patented medicine is sold at an excessive price in Canada. Our members are concerned that the proposed change will lead to increased price regulation. This policy may ultimately serve to forcibly lower

the prices of patented medicines beyond the level of international comparisons and create disincentives for Canada's biotechnology industry and their global partners to invest in research and development and introduce novel therapies in this country. BIOTECanada recommends that the Board maintain the wording of the existing mandate and not pursue the proposed changes.

Any Market Price Reviews

BIOTECanada reiterates our members' long-standing position that PMPRB does not need to regulate drug prices at the level of the provinces and territories. By expanding the price reviews at introduction to the level of any market, in addition to the three classes of customers, the Board is creating more uncertainly for patentees. The PMPRB has never provided the rationale for expanding its regulatory oversight to any market, nor have they acknowledged the resulting administrative burden for the both patentees and Board staff.

As we have stated in the past, for certain biotech products including vaccines, plasma-derived products and recombinant blood products, prices are determined through federal and provincial tendering systems, and price evaluation in any market is completely inappropriate. In the case of vaccines, the provinces, territories and Public Works and Government Services Canada (PWGSC) are sophisticated, knowledgeable and are able to use purchasing power to negotiate contracts that provide optimal arrangements in terms of price, quality, supply, and investment. Further intervention by PMPRB is not necessary.

We recommend that the Board refrain from conducting any market price reviews at introduction as this policy is unnecessary, burdensome and will only create more uncertainty for patentees.

Proposed Implementation Timelines

The current implementation timeline of July 1, 2009 is impractical. After three years of consultation on the guidelines a meaningful consensus on reporting requirements has not been reached. In light of the Judicial Review examining the PMPRB's jurisdiction over the reporting of benefits set for mid-June it is entirely possible that the Board will have to make further changes to the guidelines after July 1, 2009, as the Federal Court will likely not reach a final decision at that time.

Furthermore, there has been no mention of a transition period. BIOTECanada members encourage the Board to consider a January 1, 2010 implementation date. The complexity of the proposed amendments and the additional workload for patentees creates a challenging situation for companies to adapt to the mid-year reporting changes.

Summary

It is the view of our membership that many of the changes under consideration remain unnecessarily complex and ultimately inconsistent with the Board's mandate, as set out in the *Patent Act* to "ensure that the prices charged by patentees for patented medicines sold in Canada are not excessive." BIOTECanada believes PMPRB must return to simple, rational and logical guidelines consistent with the sprit of the *Patent Act*. Our members need a stable and predictable pricing environment if the Canadian biotechnology industry is to thrive in the future.

We are requesting that the Board continue the dialogue with Canada's biotechnology industry throughout the remainder of 2009 in order to reach a consensus on a set of amendments that position Canada as a leading jurisdiction for the introduction of advanced biotechnology therapies.

Again, we appreciate the opportunity to provide comments on the 2009 Draft Compendium and look forward to working with the Board as the consultation process continues.

Sincerely,

Peter Brenders
President and CEO

cc: The Honourable Leona Aglukkaq, Minister of Health, Health Canada
The Honourable Tony Clement, Minister of Industry, Industry Canada
Mr. Richard Dicerni, Deputy Minister, Industry Canada
Mr. Morris Rosenberg, Deputy Minister, Health Canada

Appendix: BIOTECanada Response to the Patented Medicine Prices Review Board *Notice and Comment* on the *Draft Revised Excessive Price Guidelines*

Published March 25, 2009

This appendix identifies the core concerns and recommendations of BIOTECanada member companies as they relate to the Patented Medicine Prices Review Board *Notice and Comment* on the *Draft Revised Excessive Price Guidelines* published March 25, 2009. The following comments do not necessarily represent all concerns of our membership.

1. Publication of CPI-Inflated Maximum Average Potential Price

BIOTECanada members do not see the value in publishing the Consumer Price Index (CPI)-inflated Maximum Average Potential Price (MAPP) unless it is accompanied by a true delinking of the Average Transaction Price (ATP) from the Maximum Non-Excessive (MNE) price. BIOTECanada contends 'true delinking' would allow PMPRB to set the MNE in the introductory period and apply CPI over time. As long as no class of customer paid above this CPI-inflated introductory MNE price, the price of the medicine would not be considered excessive and within PMPRB guidelines. Under the proposed changes, the MAPP could not be relied upon by PMPRB for regulatory purposes and therefore serves no obvious purpose.

2. Levels of Therapeutic Improvement

BIOTECanada commends the Board on creating a new level of therapeutic improvement which recognizes the incremental value of medicines offering moderate improvement over comparators. The Board's acknowledgment of incremental improvement demonstrates an important step in realizing the value of innovation. However, our members believe secondary factors should be permitted to move the level of therapeutic improvement from moderate to substantial improvement, which is aligned with the recommendation set forward by the Working Group on Therapeutic Improvement.

3. Introductory Price Tests

Therapeutic Class Comparison Test

BIOTECanada members are not comfortable with the proposed amendments to the Therapeutic Class Comparison (TCC) test. The draft guidelines suggest that Board staff will reference the publicly available price closest to the comparators' average selling price when conducting a TCC test. BIOTECanada members do not believe the Board should reference any price other than the highest publicly available non-excessive price. By using the Non-Excessive Average Price (NEAP), which is based on a national average price, PMPRB unfairly restricts the introductory price of a new medicine. BIOTECanada encourages the Board to use a fair and predictable price methodology that protects confidentiality and treats all patentees consistently.

International Therapeutic Class Comparison Test

BIOTECanada reiterates its position that generic drug prices should be excluded from all PMPRB price tests for branded medicines, including the International Therapeutic Class Comparison (ITCC) test. This is in line with the recommendations of the Working Group on International Therapeutic Class Comparison. The inclusion of generic prices will distort the results of the ITCC. The Board has not provided the reasons for including generics in the ITCC and fails to recognize the unique cost and price structure of the innovative biotechnology industry.

4. Any Market Price Reviews

BIOTECanada fundamentally disagrees with the Board's decision to regulate prices at the any market level. The PMPRB has never provided the rationale for expanding its regulatory oversight to any market, nor have they acknowledged the resulting administrative burden for the both patentees and Board staff. Furthermore, for certain biotech products including vaccines, plasma-derived products and recombinant blood products, prices are determined through a federal tendering system, and price evaluation in any market is completely inappropriate.

The proposed any market price review during the introductory period creates additional uncertainly for patentees while increasing the downward pressure on the prices of new

medicines relative to comparators already on the market. At introduction, the prices of products are often undiscounted as benefits and rebates are typically associated with provincial and hospital reimbursement, which does not occur at launch. Therefore, the prices of these undiscounted new medicines are compared against prices of fully-discounted products that are on the already market and being reimbursed. A further price reduction will occur when provinces and hospitals are granted discounts and rebates following reimbursement. BIOTECanada strongly cautions the Board against dissuading companies from offering any type of benefit.

By allowing market forces to bear, PMPRB will prevent significant price variations across provinces and territories. The basic economic principle of demand/supply relationship will minimize the price differences in different markets. Volume-based price differentiation must be allowed and it is consistent with free market economic rules.

5. Re-Setting the Non-Excessive Average Price After Introduction

The Board's proposed solution for re-setting the NEAP does not satisfy the concerns of BIOTECanada members. There are reasons beyond the "costs of making and marketing" for re-setting prices of Special Access Program (SAP) therapies following the issuance of a Notice of Compliance (NOC). Currently, drugs offered by companies under the SAP are often made available to patients at a reduced price or free of charge (i.e. on a compassionate basis). If re-setting the price is strictly limited to arguments based on the costs of making and marketing, many companies will have no option but to charge the highest possible price for products offered under the SAP. More clarity and flexibility around re-setting the non-excessive average price must be extended to patentees to ensure that patients are not adversely impacted.

From a practical perspective, our members are concerned that they may not be in position to provide all necessary "making and marketing" information required by the Board to re-set a price. There will be instances where companies are simply not able to disclose commercially sensitive information needed to validate such a claim.

6. Recognizing Benefits (DIP Methodology)

The proposed DIP methodology does not represent a true de-linking of the ATP from the MNE price. As highlighted in previous BIOTECanada submissions, our members still believe the proposed methodology is unnecessarily complex and will substantially increase the regulatory burden of both patentees and Board staff. In addition, BIOTECanada members are concerned that the proposed DIP methodology will impair their ability to offer benefits and negotiate reimbursement conditions with public payers. As evidenced by submissions to the Board from the Ontario Public Drug Programs and the British Columbia Ministry of Health Services, public payers do not want the Board to create any disincentives that would serve to discourage companies from offering benefits and inhibit their ability to negotiate pricing deals with patentees. Therefore, we urge the Board to implement true de-linking as this will provide a simple and transparent methodology for regulating prices. It remains BIOTECanada's view that the Board should only be reviewing prices against the CPI-adjusted MNE price.

7. Offset of Excess Revenues

BIOTECanada members do not agree with the proposed mechanism to offset excess revenues. In our view this proposal penalizes patentees twice by levying a fine and subsequently not allowing a company to take a price increase the following year. This proposal does not align with PMPRB's goal of allowing greater price flexibility and we caution the Board against creating a situation where manufacturers are encouraged to take all allowable CPI increases each year, which is not the current practice of patentees, or in the best interests of Canadian consumers.