BIOTECanada

October 6, 2008

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

Dear Dr. Benoit,

BIOTECanada appreciates the opportunity to make a submission to the Patented Medicine Prices Review Board (PMPRB) in response to its *Notice and Comment* document regarding the *Draft Revised Excessive Price Guidelines* released August 20, 2008.

Through previous submissions and continued discussions with the Board and Board Staff on the review of the Excessive Price Guidelines dating back to May 2006, BIOTECanada has shared the views of our membership with PMPRB, specifically highlighting the core concerns of the biotechnology industry related to the proposed regulatory changes. While we appreciate the on-going outreach on behalf of the Board to engage BIOTECanada, our members continue to seek clarity on the fundamental purpose and objectives of the consultations to date and the underlying rationale for the proposed changes to the Guidelines.

We contend that many of the proposed changes remain overly vague and create an unnecessary level of uncertainty for our membership. In some cases, the proposed changes to the Guidelines are entirely inappropriate for our members' products. Specific details and comments are provided in the Appendix to this letter. We remain most concerned about the negative impact these changes may have on patient access to important new therapies. We caution the Board on inadvertently creating disincentives to the development and launch of innovative biologics in Canada, leaving Canada's most vulnerable patient populations with fewer therapeutic options.

Based on information provided to our members on the September 9, 2008 teleconference call with Ms. Barbara Ouellet, we were encouraged to hear the following:

1. The definition of a "sales transaction" is not defined in the *Patent Act* and as a result PMPRB does not have or adhere to a specific, legal definition. The onus is on individual patentees to determine what constitutes a sale; what is connected to a sales transaction; and therefore what pricing information to include or exclude as it pertains to compliance under the regulations.

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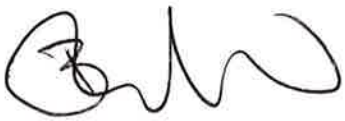
2. The Board's jurisdiction over the treatment of free goods is "limited to patented medicines that are being or have been *sold* in any market in Canada…and any benefits not connected to sales are not to be reported for the purposes of the Board's consideration of factors in 85(1) of the Act." Therefore, provided there is no sale, as defined by the patentee, no reporting is necessary.
3. Patentees may continue to support patients through compassionate care programs without being penalized for offering products free of charge as these products will have no bearing on the determination of Average Transaction Price (ATP) or Maximum Non-Excessive (MNE) price, as they are not connected to a sale.
4. No additional reporting requirements on behalf of the patentee are required as companies would not be required to provide information beyond current class of customer data.

Should the above four points hold true it would appear that there is little need for the sweeping changes proposed in the *Notice and Comment* document. Again, the rationale for the numerous amendments is not evident. In light of the uncertainty introduced by the Board's proposals and the far-reaching implications for both patentees and the Canadian public, we request the Board refrain from implementing the proposed changes and new reporting requirements pending further discussions between PMPRB and the biotechnology industry.

BIOTECanada Board members accept the invitation to meet with the Board on October 22, 2008 and look forward to further discussions on these important issues.

Sincerely,



Peter Brenders
President and CEO

cc: Sylvie Dupont, Secretary of the Board

Appendix: BIOTECanada Response to the Patented Medicine Prices Review Board *Notice and Comment* on the *Draft Revised Excessive Price Guidelines* published August 20, 2008

The following comments represent the views of BIOTECanada member companies. This submission identifies the core concerns and recommendations of our membership with respect to the Patented Medicine Prices Review Board ("PMPRB" or the "Board") *Notice and Comment* document regarding the *Draft Revised Excessive Price Guidelines* published August 20, 2008.

1. Underlying Principles

BIOTECanada members have concerns related to the Board's expanded regulatory mandate, which centres on "protecting consumers and contributing to Canadian healthcare." This language is not contained in the *Patent Act* and PMPRB has yet to provide the underlying rationale for this broadened interpretation of their role. We believe the Board's role, as set out by the *Act*, is to ensure that prices of patented medicines are not excessive and referring to consumer protection will only create confusion about its mandate.

2. Levels of Therapeutic Improvement

BIOTECanada agrees with the recommendations developed by the Working Group on Therapeutic Improvement (WG-TI). Specifically, our members support the addition of a new level of "Moderate Improvement" provided the relevant price test is more flexible than the existing price test for such drugs. The Board's acknowledgement of incremental improvement is an important step forward in realizing the value of innovation.

However, we are discouraged by the Board's decision not to include all of the secondary factors recommended by the WG-TI. We agree with the WG-TI that it is appropriate to include compliance improvements in the assessment of therapeutic improvement, but are disappointed that the Board wants to consider this factor "only if it leads to improved therapeutic efficacy." The Board's position fails to consider the challenge of conducting clinical trials to assess the

therapeutic benefit of compliance. By definition, all subjects within a well-controlled and well-designed clinical trial are compliant. Thus, providing clinical data to support improved therapeutic efficacy is essentially impossible. In the view of our members it is unacceptable that compliance improvements should only be considered if there is evidence of improved therapeutic efficacy. BIOTECanada strongly recommends PMPRB reconsider incorporating patient compliance in the assessment of therapeutic improvement.

3. International Therapeutic Class Comparison Test

BIOTECanada agrees that the International Therapeutic Class Comparison (ITCC) test should only be utilized under those circumstances where its use may result in the resolution of a dispute, thus avoiding the need for a hearing. As is the current practice of the Board, we do not feel the ITCC test should be used for price calculations of new, patented medicines under normal conditions.

BIOTECanada members do not believe the decision by the Board to include generic drug prices in the calculation/application of the ITCC test is appropriate. In concordance with the recommendations put forward by the Working Group on International Therapeutic Class Comparison (WG-ITCC) our membership urges the Board to exclude generic drug prices from the ITCC test.

4. Introductory Price Tests

BIOTECanada members have considerable concerns related to the proposed changes to the Reasonable Relationship (RR) test and the Therapeutic Class Comparison (TCC) test. The Board did not consult patentees on these proposed changes, nor was any justification for the changes highlighted in the *Board's Position* in the *Notice and Comment* document. The proposed draft Guidelines do away with the existing provisions that provide alternatives when the RR test or TCC test are not considered appropriate. BIOTECanada members recommend the Board recall these provisions until further consultation is conducted and patentees have been provided with the underlying rationale for the proposed changes.

The principle that Board Staff will use an "appropriate public source for the prices of comparable products" determined on a case-by-case basis to calculate introductory price using a TCC test

allows for too much uncertainty. Patentees working to establish acceptable introductory prices within the Guidelines need greater clarity on this point. The Board should adopt as policy the conclusions it reached in the recent *Adderall XR* matter to use the highest domestic publicly-available prices for comparator drugs.

5. Modified Guidelines for Certain Generic Drug Products

Prior to making this submission BIOTECanada was not provided an opportunity to comment on this issue. It is the view of our membership that the Board's special treatment of generic patentees during this consultation process was unfair and ill advised. All of the PMPRB Working Groups, with the exception of the Generic Drug Product Working Group, included representation from each of the following key stakeholders: provincial health ministries, consumer groups, patentees (including BIOTECanada) and others. The exception was this separate Generic Drug Product Working Group, which only involved representatives from PMPRB and the patented generic industry. From a procedural standpoint, our members urge the Board to redress the lack of openness and transparency and hold generic patentees to the same standards as innovative patentees. Special treatment should not have been extended to one segment of the industry over another.

6. Impact of Reporting Benefits (De-linking of the ATP from the MNE Price)

The proposed de-linking methodology in the draft Guidelines does not represent a true de-linking of Average Transaction Price (ATP) from the Maximum Non-Excessive (MNE) price. It is unnecessarily complex and will only serve to increase the workload of both patentees and Board staff.

BIOTECanada members are concerned that the proposed methodology will negatively impact their ability to offer compassionate programs and to negotiate reimbursement conditions with public bodies. In fact, the proposed requirements to report all benefits including compassionate care drugs will likely force companies to discontinue offering free goods in order to maximize their ATP. This approach of using the net ATP as the benchmark price is re-setting the MNE each year. Under true de-linking, the national MNE price should never decrease and in fact should only increase over time with reference to the Consumer Price Index (CPI). It is our view that the Board should only be reviewing prices against the CPI-adjusted MNE price.

BIOTECanada supports the principle of true de-linking as this will provide a simple and transparent methodology for regulating the price of biotechnology products. However, the Board's guiding principles behind this methodology are not well articulated. The Board has not clearly stated their intention on this issue and have indicated that further analysis is required.

Given the current uncertainty around the proposals, our members strongly feel that further discussions on the issue of de-linking MNE and ATP are needed before any changes are implemented.

7. Any Market Price Review

BIOTECanada has continually advocated that the Board does not need to regulate prices at the any market level. Prices for certain biotech products including vaccines are determined through a federal tendering system. Currently, there is very little price discrepancy among provinces. Furthermore, volume-based price differentiation should be allowed, as it is consistent with economic rules. The vast majority of all stakeholders involved in this consultative process share our opinion. The broad-based application of any market reviews will place downward pressure on prices. Therefore, patentees many decide to no longer offer any discounts or benefits because they will be forced to maintain prices to all customers at the highest possible level.

The Board's decision to conduct any market price reviews "on a case-by-case basis where price variability in different markets appears to be an issue" creates a great deal of uncertainty for patentees. Although we recognize the Board always retains the right to review prices in any market, manufacturers need to understand the criteria/conditions that trigger a review at the any market level. Our members remain concerned that any market reviews will be conducted with greater frequency and less predictability, which will have the adverse effect of not allowing companies to clearly understand how their pricing decisions/agreements will be ruled upon. This level of uncertainty will undoubtedly result in less desire to provide benefits. We do not agree with the Board deciding these questions retroactively.

8. Re-setting the MNE Price

BIOTECanada accepts the decision of the Board to maintain the current approach for re-setting the MNE price, by reviewing the median international price within three years or once the

product is sold in five comparator countries. However, we disagree with the omission of the existing provisions for re-setting the MNE price when a product is sold under the Special Access Programme (SAP). Patentees should retain the option to re-set the price of their product at Notice of Compliance (NOC) if SAP sales have occurred prior to approval. Lack of flexibility in this area will hurt those Canadians on SAP therapies through higher prices and reduced access.