November 2, 2007

Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Re: BIOTECanada-PMPRB Bilateral Meeting Follow-up Submission

Dear Ms. Dupont:

BIOTECanada is the national association representing the broad spectrum of biotech constituents including emerging and established companies in the health, agricultural, and industrial sectors, as well as academic and research institutions and other organizations dedicated to the long term and sustainable development of biotechnology, its practices and products.

BIOTECanada appreciated the opportunity to meet with Board members directly on September 11th in order to present our positions on the Excessive Price Guidelines. We appreciate the openness of the dialogue and will continue to engage with the Board as the consultation process continues. Our members would like to re-iterate our specific concerns as set out in our submission of August 25, 2006 and in our meeting on September 11, 2007.

PMPRB Policies on Compassionate Use Program – Dovobet Case

BIOTECanada acknowledges that on October 18, 2007, in a Board Communiqué, the Board indicated that it is committed to continuing its work with stakeholders on resolving the issues arising from the LEO Pharma decision, including assessing possible options for amendments to the *Patented Medicines Regulations* (the "Regulations") and its Excessive Price Guidelines. We note that this position was stated again in the October 2007 PMPRB NEWSletter.

The position of BIOTECanada on this issue is very clear. We believe that the status quo must be maintained and to the extent that the maintenance of the status quo requires changes to the Regulations those changes should be obtained without delay.

In this regard, we would restate our concerns with the proposed amendments to the Regulations in respect of the reporting of the type of rebate or discount included in the average price calculation that were pre-published in the Canada Gazette, Part I on October 6, 2007. In our view, it would be premature to promulgate the proposed amendments in the absence of a consensus around what should be done to resolve issues arising from the LEO Pharma decision.

Principles

According to the *1987 Patent Act Amendments* (Bill C-22), the mandate of PMPRB is to ensure that the prices charged by patentees for patented medicines are not excessive. BIOTECanada believes that PMPRB has managed to fulfill, or even exceed, its mandate using the existing Guidelines in the past. The Board's policies should be consistent with its fundamental mandate.

The incentives for creating PMPRB included stimulating innovation/research activities and improving accessibility to new medicines in Canada. It is not in the best interest of Canadians if the Board makes guideline modifications that will potentially discourage investment in research and development (R&D) activities. Such modifications create conflicts with Parliament's original intent for amending the *Patent Act* in 1987.

Categorization

As indicated in the May 31st Communiqué, the Board is examining the possibility of establishing definitions or parameters to recognize the value of "moderate improvement." BIOTECanada believes that the best approach to recognize the value of innovation, however, is to simplify the current price review system by implementing a single category for all products. The Board should eliminate categories and should only be involved in assessing breakthrough drugs since market forces automatically take care of prices for following entrants. In addition, product categorization is a complicated process that requires extensive examination of a product's clinical evidence. Such activities duplicate the responsibility of Health Canada. PMPRB should have no role vis-à-vis the clinical effectiveness of a product.

International Therapeutic Class Comparison

To determine the excessiveness of introductory prices, the Board has indicated its interest in identifying appropriate therapeutically comparable medicines in comparator countries.

Given the already complicated process in finding "comparable medicines" in Canada for the purpose of the Therapeutic Class Comparison (TCC) test, it would be more difficult to identify comparable medicines, dosage forms and dosages in a foreign country. Different countries do not always share identical medical practices or the same approved indications/criteria for use of a given product.

BIOTECanada believes, in order to be consistent with its mandate, the PMPRB must exclude generic products as comparators in both domestic and international therapeutic class comparisons. Brand name manufacturers will face insurmountable difficulties in launching new products in Canada if generics are used as comparators. R&D activities will be strongly discouraged and the ability of the Canadian public to access new innovative medications will be limited.

Price Tests

Considering the uniqueness of biotechnology products, the Board should allow price tests to be implemented with increased flexibility. Biotech products are unique and often address unmet needs. In many cases, the size of the market is small, the costs of development are high and there are few or no truly comparable products. In many cases, the current guidelines are not appropriate for reviewing the introductory prices for new patented biopharmaceutical products in Canada. For example, vaccines, plasma-derived products, and recombinant blood products use scarce materials and have limited global supplies each year. To accommodate these specialties, provincial and national jurisdictions use a tender process for these products and negotiate prices that are not excessive. 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 for these products. Further intervention by PMPRB is not necessary.

Making and Marketing Costs

According to the May 31st Communiqué, "While, to date, the Board **has not** had to give consideration to subsection 85(2) to make a determination of excessive pricing, it recognizes the situation could arise."

BIOTECanada does not understand the Board's intention to do further work on this issue. We believe in order to keep the review process simple and direct, such situations should be handled on a case-by-case basis. We would call the Board's attention to the difficulty in calculating such costs. It is possible that such information may not be available to the patentee or may not be within the knowledge and/or control of the patentees in Canada.

As more products are produced and marketed internationally it is becoming increasingly difficult to allocate an accurate proportion of costs and to determine the marketing impacts for each country. Because of the strict safety and efficacy regulations in biotech and pharmaceutical industries, a very low percentage of drug candidates are commercialized. Profits from one successful product are used to finance the research and development for several pipeline products. Using making and marketing costs to determine introductory prices will significantly limit the potential of future innovation.

Price Increases

The Board has decided the current CPI methodology is sound and it will only propose changes where the MNE price calculated for the year under review is less than or equal to the average transaction price of the previous year. **BIOTECanada believes that, in addition to these** circumstances, other factors could also create conflict with the intent of the Act.

CPI is a benchmark that reflects price changes in Canada only. For products such as vaccines, plasma-derived products and recombinant blood products that compete for raw materials on a global level, CPI could limit the competitiveness of manufacturers.

CPI is a benchmark for the overall price change of products from all industries. It does not reflect the year-over-year price variation of all biotechnology products in a global market with scarce resources. In 2004, the Canadian Blood Product Industry sent a policy paper, Price Review of Patented Blood Products, to the Board. In this paper, experts from the industry illustrated the difference between blood products and traditional products from several aspects. As an example, different mechanisms are used to manage traditional products versus resource-based products. CPI is a reliable figure for traditional products, for which the supply-demand relationships are generally managed through an adjusted level of production. Blood products are more closely related to resource-based products (e.g., oil) in nature. Production is adjusted at significant higher costs for such products due to the limited worldwide availability of the raw material.

The CPI methodology cannot reflect the aforementioned characters of biotechnology products such as vaccines and blood products. To reduce the regulatory burden, and to increase the global competitiveness of Canadian industry, the Board should not enforce CPI tests to these products. The tender process and buying system currently used are more appropriate, and sufficient, methods for these products.

Price "Re-benching"

The Board has indicated its desire to keep the review process simple and easy-to-follow. To be consistent with this message, BIOTECanada believes the Board should consider price "re-benching" in the situations already identified in the guidelines and, in other situations, only on a case-by-case basis.

"Any Market"

BIOTECanada members would reiterate the position that PMPRB does not need a new methodology for regulating prices in "any market." "The PMPRB is responsible for regulating the prices that patentees charge… **to wholesalers, hospitals or pharmacies**, for human and veterinary use to ensure that they are not excessive." Furthermore, market forces will help to prevent significant price variations across provinces. The basic economic principle of demand-supply relationship will minimize the price differences in different markets.

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 not necessary. There is currently little price discrepancy among provinces for such products. Customers such as wholesalers, hospitals, or pharmacies also have the option to join national group purchasing organizations such as Medbuy and HealthPRO. Such organizations negotiate purchasing contracts on behalf of their members at a national level.

Again, we appreciate the opportunity to clarify the positions of Canada's biotechnology industry on the proposed amendments to the Excessive Price Guidelines. We look forward to working with the Board as the consultation process continues to ensure that Canada remains a preferential jurisdiction for the introduction of the most advanced biotech products and vaccines.

Sincerely,

Peter A. Brenders
President and CEO