BIOTECanada

March 3, 2008

Sylvie Dupont
Secretary to the Board
Patented Medicine Prices Review Board
333 Laurier Avenue West Suite 1400
Ottawa, Ontario K1P 1C1

Dear Ms. Dupont:

BIOTECanada appreciates the opportunity to make a submission to the Patented Medicine Prices Review Board in response to its Discussion Paper, "Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines" which was released on January 31, 2008.

Through our previous submissions and on-going discussions with the Board and Board Staff on the review of the Excessive Price Guidelines and the *LEO Pharma – Dovobet* matter, we have provided the Board with suggestions that in the view of our members would allow the PMPRB to meet its statutory mandate of ensuring the prices for patented pharmaceutical products in Canada are not excessive.

We appreciate the inclusion of a clarifying regulatory provision supporting BIOTECanada's position that reporting of payments to third-party payers is not required. We also appreciate the recognition of regulatory and supply costs within the price re-setting discussion. Overall, however, our members remain concerned that the Discussion Paper has not addressed several of the core concerns that we have identified in the consultations to date.

- The regulatory options presented in reference to the Federal Court Decision on *Leo Pharma – Dovobet* do not adequately preserve incentives for manufacturers to offer compassionate programs and in fact they seriously jeopardize future access to medicines that may benefit thousands of Canadians.

- The proposed guideline changes to the CPI methodology do not represent a true de-linking of the Maximum Non-Excessive Price from the Average Price.

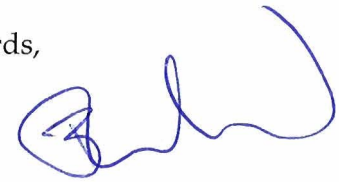
- The proposed guideline changes to conduct "Any Market Price Review" are unnecessary given the Board's current ability to review prices in any market in Canada.

- Re-benching should be considered on a "case-by-case" basis as is current practice.

We have pointed out the unique characteristics of the markets for biotechnology products and explained why we consider that many of the guideline proposals and regulatory options are inappropriate for our members' products. Moreover, we remain concerned about a dampening effect 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.

We provide more detail on our concerns with the possible policy directions below. We look forward to further discussions with the Board on these important issues.

Regards,



Peter A. Brenders
President & CEO

Attachment

BIOTECanada Response to January 31, 2008 Discussion Paper

The following comments represent a summary of the views of BIOTECanada and its member organizations on the Discussion Paper, "Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines" which was released on January 31, 2008.

LEO Pharma – Dovobet

The Discussion Paper describes eight options to amend the regulations and the guidelines to address the questions raised by the Federal Court decision in *LEO Pharma - Dovobet*. As mentioned in previous submissions and in meetings with the Board and Board staff our members are concerned about the impact of the proposed options on the ability of manufacturers to provide innovative therapeutics on a compassionate basis to Canadian patients. The Discussion Paper does not address the specific concerns or impacts of the proposals on compassionate programs and we remain convinced that if implemented, the proposed regulatory options will create disincentives for manufacturers to offer such programs to Canadian patients.

As we have stated previously and as was noted in the legal brief we provided, we believe that the Federal Court decision does not require the proposed regulatory changes presented in the Discussion Paper. We believe that the status quo policy has worked and continues to be appropriate. Under the status quo, patentees can opt to include or exclude products supplied under compassionate release and other special programs from the calculation of the Average Price provided they do so on a consistent basis. We understand this policy was adopted by the Board specifically to ensure that the guidelines do not discourage compassionate programs.

The uncertainty about this policy is already causing our member companies to re-evaluate future compassionate programs for innovative therapeutics. We would support a confirmation of the status quo option at the earliest opportunity to provide certainty for manufacturers and patients. If the Board considers that the maintenance of the status quo requires changes to the Regulations, we would be pleased to work with the Board in this regard.

Our members welcome the option identified by the Board not to include payments to third party payers in the calculation of the Average Price under Option 2. As we have suggested in our previous submissions and meetings, inclusion of such payments were never contemplated by the Regulations and we welcome a clear statement by the Board in this regard.

We also support the concept of "de-linking" the Average Price and maximum non-excessive (MNE) price for purposes of the guidelines as discussed in meetings with Board Staff. Unfortunately, the guideline changes proposed in the Discussion Paper do not include this option.

"De-linking" refers to establishing the MNE price at launch based on the appropriate excessive price tests and then adjusting it annually based on changes in the Consumer Price Index (CPI). It would do away with adjusting the MNE price each year based on the Average Price in an earlier year. This model is fully consistent with the Board's excessive price mandate, is much less cumbersome than the current methodology and the options presented in the paper, and would preserve incentives for compassionate programs. We urge the Board to consider this option as part of the discussion on resolving the Federal Court decision on *Leo Pharma – Dovobet*.

Review of the Excessive Price Guidelines

The Discussion Paper sets out specific proposals from the Board on two issues and provides an update of work on the remaining six issues. We believe many of these issues, or the proposals arising from them, are inter-related. The inter-relationships add to the complexity of the issues raised and make it difficult for stakeholders to analyze and comment on them in the short time allowed.

For example, the "re-setting" proposals would introduce the element of the "costs of making and marketing" a medicine as a criterion, but the Board is doing a separate policy review of this topic which will not be completed for some time. As a result, we do not know what, if any guidance might be developed by the Board on this topic. Also, several of the proposals involve reference to Health Canada's Progressive Licensing Framework initiative, but this initiative has not been fully developed and the timing of its implementation is unknown. Similarly, the proposals on "any market" could be affected by decisions on other issues involving the calculation of the Average Price and MNE price as discussed above.

Any Market Price Review

We continue to be concerned about the Board's proposals to institute a submarket, market-by-market price review. In previous reports, and even in the Discussion Paper itself, the Board has stated:

> In the 2006 and 2007 consultations, stakeholders expressed the view that, if price reviews are conducted at the level of any market, they should be undertaken, on a case-by-case basis, where appropriate.
> ...
> In its May 31, 2007, *Stakeholder Communiqué* the Board agreed with this approach and committed to identifying circumstances where it may be appropriate to review prices in any market in Canada.

We have previously stated our position that it is neither necessary nor appropriate for the Board to move away from its current approach of reviewing an Average Price in Canada. This approach is appropriate given the Board's mandate to ensure prices are not excessive; and market forces have ensured that there are no significant price variations across provinces. In

addition, there are some specific markets for biologics such as blood products and vaccines where national buying and tendering systems provide adequate safeguards to ensure non-excessive prices.

Despite the statements of the Board that it agrees with a "case-by-case" approach to any market price review, the proposal effectively creates extensive new regulatory and administrative burden for patentees and the Board. In essence, patentees seeking to comply with the guidelines and avoid the potential for enforcement action would be forced to monitor their prices in each and every submarket on an ongoing basis, thereby significantly increasing the complexity and the cost of compliance. Considering the low amount of price variability that the Board has historically seen across markets, this would appear to be a wasteful exercise.

We are concerned that this proposal will actually result in higher prices for therapeutic products overall in Canada as patentees find themselves constrained from offering volume discounts, or price incentives. The impact could be particularly significant in the hospital market where buying groups and tendering practices have often brought about lower prices for those institutions. Given the amount of uncertainty for both patentees and their customers as a result of this policy change we encourage the Board to retain its current effective approach of case-by-case reviews.

Re-Setting the MNE Price

In previous submissions we have supported the Board's desire to keep the price review process simple and easy-to-follow. The best way of doing that is to maintain and apply the current provisions for "re-benching" in the guidelines and otherwise to re-set MNE prices only on a case-by-case basis as may be warranted by the facts. Situations suggested by the proposal such as new government regulation costs or new supply costs can be addressed by the Board in a case-by-case approach.

The proposal to restrict the circumstances when the MNE price may be adjusted after a drug is sold under a Special Access Program (SAP) presents a significant concern to suppliers of biologics. The complex nature of the manufacture and regulatory approval of such drugs means that physicians often request authorization under SAP before the drug is approved for sale. Manufacturers wish to be able to respond positively to such requests.

The current guidelines provide adequate safeguards for the Board to ensure that the new price at the time of the NOC is consistent with the guidelines for new drugs. The proposal to limit the re-setting of the MNE price of a drug sold under SAP to circumstances where the Board will be satisfied that the price is lower than the "actual costs of making and marketing the approved drug" would impose an unrealistic and uncertain standard. The effect will discourage a manufacturer from offering patients and physicians an early access to new therapies.

The proposal to re-set the MNE price based on new scientific evidence also creates additional uncertainty. It is unclear what scientific evidence would be considered in this re-evaluation or under what criteria the data would be analyzed. The reference to rare disease therapeutics is also troubling. It is not clear if the Board is proposing a different standard of evidence for rare diseases or if the Board expects that data similar to non-rare disease therapeutics would be forthcoming at some later point in time.

In sum, the Board's proposals for re-setting the MNE price will result in more rather than less uncertainty for both patentees seeking to introduce novel therapeutics into Canada and more importantly for the patients who are desperately waiting to access treatments for life-threatening diseases. Our members recommend that the Board retain its current case-by-case approach to re-benching or more fully describe the compelling case to move to a new approach.

Conclusions

BIOTECanada wishes to reiterate its appreciation for the opportunities to consult with the PMPRB on the current review of the guidelines and the response to the *Leo Pharma* decision. We remain concerned about the breadth of these activities and the messages they send to the biotechnology sector in Canada and abroad about ongoing uncertainty in the pricing environment in Canada. This uncertainty, and fears that the system will become more restrictive and more complex, creates barriers to investment in Canada and to the introduction of new therapies.

Overall, a more complex and uncertain pricing environment will lead to a delay or possibly no access to new biologic products for Canadian patients – an outcome counter to the Board's desire for "consumer protection" and BIOTECanada's mission dedicated to the sustainable commercial development of biotechnology in Canada.