JANSSEN-ORTHO

October 12, 2007

Dr. Brien G. Benoit, MD
Chairperson
Patented Medicines Prices Review Board
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Dear Dr. Benoit:

I would like to thank the Board for the opportunity to participate in its bilateral meetings with stakeholders on September 11, 2007 as a representative of Janssen-Ortho Inc., Ortho Biotech, and in my capacity as Chair of the Health Policy Board for BIOTECanada.

Janssen-Ortho and Ortho Biotech are members of Rx&D and BIOTECanada respectively and endorse the submissions those associations have made to the Board during the course of its consultations on the Excessive Price Guidelines. In addition, we have made submissions in the form of a letter from Mr. Chris Halyk, President of Janssen-Ortho of September 25, 2007 and in Janssen-Ortho's submission of August 25, 2006 in response to the Board's Discussion Guide published in May 2006.

During the course of these consultations, there have been increased opportunities to consult with the Board on PMPRB pricing policy matters and we look forward to opportunities for continued and constructive dialogue.

Canada's biopharmaceutical industry has been experiencing a period of rapid change in recent years, particularly in the area of market access, pricing and public reimbursement policies. These changes include new legislation and policies in Canada's largest provinces, Ontario and Quebec, with changes in other provinces now under way; the increasing challenges in the Common Drug Review and more recently the Joint Oncology Drug Review; and, in general, the dynamics of increasing globalization in pharmaceutical markets. In this environment, the ongoing consultations by the PMPRB on its Excessive Price Guidelines have contributed to a concern that the Board may ultimately adopt even more restrictive price guidelines. This concern has been heightened by the expansion of the scope of the consultations to include most of the key elements of the Guidelines, the proposals to amend the *Patented Medicines Regulations,* and the policy statements in the April 2007 NEWSletter. While policy review is necessary and appropriate from time to time, it may also have a negative impact by creating uncertainty in the market that impacts investment and marketing decisions into future years.

The current Guidelines of the PMPRB and the manner in which they are being applied by Board Staff create disincentives to develop and introduce new medicines that provide incremental improvement over existing therapies. Since the Board has decided to open up the Guidelines for review, we believe this is an appropriate time to address this issue. In its Stakeholder Communiqué of May 31, 2007, the Board indicated that it wishes to proceed with further work on questions such as the definitions of categories of new medicines, including definitions of moderate improvement; questions related to international therapeutic class comparisons; and other issues, but it has decided to reserve any further consideration of appropriate price tests pending that further work. We are concerned that real progress on these questions will be hampered without a clearer indication from the Board of its approach to an appropriate

excessive price standard for drugs that offer an incremental improvement over existing medicines. More specifically, it would be helpful if the Board indicated that it supports the principle that the Guidelines should not limit the prices of new medicines that offer an improvement over existing drugs to the prices of those drugs.

Although the purpose of the bilateral meetings in September was to discuss the review of the Excessive Price Guidelines, we also took advantage of the opportunity to raise our ongoing concerns with respect to other issues, including the announcements in the April 2007 NEWSletter concerning the interpretation of the Federal Court decision in the Dovobet case and the proposed treatment of payments to provincial governments pursuant to confidential agreements mandated under provincial legislation. In prioritizing the work ahead of us, we would encourage the Board to focus on these latter issues which have an immediate and direct impact on business plans and the marketing decisions of manufacturers.

We look forward to the opportunity to work with the Board and Board Staff through ongoing consultative mechanisms to address these and other issues in the coming months and will continue to encourage the Board to attempt to resolve the more pressing issues within a prompt and predictable period of time.

In our view, the PMPRB is most effective in fulfilling its mandate under the *Patent Act* by focusing its attention on its statutory mandate to ensure that prices of patented medicines are not excessive, taking into account the factors in the *Act* and the broad context of the pharmaceutical market in Canada which is characterized by competition and the policies of public drug plans. The PMPRB must exert great care to ensure that it does not exceed its mandate and through its policies detract from the other objectives of the *Patent Act* and government policy to promote and encourage innovation in Canada's biopharmaceutical sector.

You may be assured of our continued willingness to consult and work with the Board in addressing these challenges.

Kind regards,

HWilson

per: Lesia M. Babiak, BscPharm, PharmD, MBA
Director, Federal Affairs & Health Policy