Bayer Inc.

October 6, 2008

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

Philip Blake
President and CEO

Dear Dr. Benoit:

I am writing to provide the views of Bayer Inc. on the PMPRB's Notice and Comment package on the Draft Revised Excessive Price Guidelines released on August 20, 2008. Bayer supports the submissions of Rx&D and BIOTECanada on this package and we are providing this letter with our specific comments.

Bayer has been an active participant in this consultation process since it was first initiated in May 2006, both through company-level written responses, submissions through our industry associations and through face-to-face meetings. We were deeply dismayed to see that in this latest proposal the Board has once again overlooked the significant feedback that we and other stakeholders have provided. This package of proposals is unworkable, overly complex and reaches beyond the mandate of the PMPRB and for that reason Bayer can not support it.

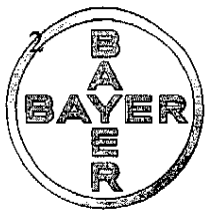
Bayer Inc.
77 Belfield Road
Toronto, ON M9W 1G6

Tel. (416) 248-3000
Fax (416) 248-6768
philip.blake.b@bayer.com

Throughout these consultations, PMPRB has not provided a rationale for why an overhaul of the guidelines is needed. In fact, in the PMPRB's Annual Reports, the Board has consistently reported a high rate of compliance and stable prices for patented medicines that are in the mid-range of prices in other countries. For this reason, we question the need for the proposed expansion of price controls.

It is important to note that these proposals would represent an unprecedented level of intervention in the pharmaceutical market – and would, in fact, introduce a degree of price control that is unequalled in any other sector of the economy. This despite the fact that over the past 16 years, pharmaceutical prices on average have not increased by more than the Consumer Price Index. It is not clear what problem the PMPRB is seeking to address.

Furthermore, through additional reporting requirements these proposals would add considerable administrative burden to companies that is unnecessary and unjustified. This runs counter to the policy objectives set out in the federal *Cabinet Directive on Streamlining* (April 1, 2007). Finance Minister Jim Flaherty has also made comments to companies, including Bayer, clearly stating that the Government is aiming to reduce (not increase) regulatory burden wherever possible.



Bayer Inc. does not have approval from our global headquarters for additional head count to fulfil these proposed requirements. If we as a company are required to resource this proposal, we would be forced to shift human resources from critical functions such as research and expenditure on new agents to fight disease. This is clearly not achieving an outcome in the public interest.

The proposals for detailed price control are not consistent with the policy objectives of the pharmaceutical pricing provisions of the *Patent Act* which give the Board authority to review prices to determine if they are excessive. Given Bayer's track record of compliance, we simply don't see the need for this expansion of regulatory oversight.

To make matters worse, the proposals will create distortions in the market and limit the flexibility for patentees to respond to market forces and to offer compassionate access programs for patients. By creating disincentives to volume discounts and other pricing arrangements, the proposals will have the perverse effect of discouraging competition among patentees and will put an upward pressure on prices. Bayer directly experienced this limited flexibility when we were forced to withdraw our compassionate use programs for Nexavar in renal cancer following the Board's April 2007 Newsletter (see Bayer letter dated May 10th, 2007).

We are concerned by the unpredictable, unfocussed and increasingly combative approach taken by the PMPRB in recent years. One symptom of this approach is the increased reliance on contested hearings rather than dispute resolution. In the 18 years from 1987 to 2005, the PMPRB commenced formal proceedings in eight cases and only two of those required a full hearing by the Board to make a determination on excessive price. In less than three years since then, the Board has initiated 12 hearings and most of these have required, or are expected to require, a full hearing.

As a corporate taxpayer, we are extremely disconcerted by the rapid escalation of the PMPRB budget that has resulted from this new approach. Since the 2005-2006 fiscal year, the PMPRB has grown from a budget of $5.6 million to $11.5 million in 2007-08 – an increase of over 100% in 2 years. This is clearly out of step with efforts by Government to limit increases in public spending and allocate tax dollars to areas of greatest public good.

Furthermore, the uncertainty created by these lengthy consultations on the Guidelines and confusion around the reporting requirements under the Regulations creates instability that negatively affects business planning and hampers Bayer Inc.'s ability to attract global investment for R&D in Canada within the Bayer global community.

Bayer strongly recommends that the PMPRB set aside the package of proposals set out in the consultation package of August 20, as it is unworkable, overly complex and reaches beyond the mandate of the PMPRB. It is Bayer's position that the PMPRB should strictly respect the intent of the Patent Act and the resulting legislative mandate to prevent excessive pricing and encourage innovation.

Sincerely,

Philip Blake
President and CEO

cc. Hon. Tony Clement, Minister of Health
Mr. Morris Rosenberg, Deputy Minister of Health
Mr. Richard Dicerni, Deputy Minister of Industry
Mr. David Moloney, ADM, Industry Sector, Industry Canada
Mr. Kevin Lynch, Clerk of the Privy Council
Mr. Matthias Höpfner, Ambassador of Germany to Canada
Mr. Peter Boehm, Ambassador of Canada to Germany
Provincial Deputy Ministers of Health