Bayer Inc.
77 Belfield Rd.
Toronto, ON
M9W 1G6
Tel. (416) 248-0771
Fax (416) 240-5292

By e-mail: sdupont@pmprb-cepmb.gc.ca

November 6, 2007

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

Dear Ms. Dupont,

Bayer Inc. is pleased to have the opportunity to provide written comments to follow up on the consultative meeting in which I participated on September 10th, 2007.

Bayer Inc. is a Canadian subsidiary of Bayer AG, an international research-based group with core businesses in health care, crop science and innovative materials. Our health care business in Canada includes pharmaceuticals, consumer care, diabetes care, biological products and animal health.

Bayer is a member of Canada's Research-based Pharmaceutical Companies (Rx&D) and supports the submission of Rx&D in the context of these consultations. In our submission, Bayer would like to highlight the following areas.

GENERAL COMMENTS

Proliferation of Issues

The recent increase in the number of pricing policy issues under review by the PMPRB and other issues on which the PMPRB and patentees have differences of opinion is of concern since it increases uncertainty. We share Rx&D's concern that the continuation of this environment will have a negative impact on the development and introduction of new

medicines in Canada, to the detriment of Canadians and our health care system, and we encourage the Board to attempt to resolve these issues as quickly as possible.

In addition to the number of issues, we are concerned that PMPRB appears to be attempting to address these issues in silos and this approach does not recognize the linkages among the issues. In that context, we wish to note that while the focus of this submission is to address the questions raised by the Board in its May 2007 Stakeholder Communiqué, we consider that many of these issues have implications for other issues that are either under consideration or are the subject of separate discussions with the Board.

Respecting PMPRB's Mandate

Bayer shares the concern of Rx&D and other member companies that the Board is undertaking initiatives that appear to keep moving it further away from its mandate as established by Parliament through the Patent Act.

PMPRB's role is to establish and monitor the patented medicine prices in Canada. We believe this should be the only role. Over the years, the Board has fulfilled this role and has ensured that the Canadian prices for patented medicines are non-excessive. However, the Board appears to have evolved from carrying out an oversight role with respect to the prices of patented medicines to a more direct role in the day to day business activities of patentees. We are concerned that many of the issues under review through these consultations, along with other issues raised in recent years, represent an attempt by the Board to intervene in the pharmaceutical market in ways that were not contemplated by Parliament and the Patent Act and which are unnecessary in the context of the Board's mandate.

We also share Rx&D's view that the PMPRB's activities in recent years suggest that it has lost sight of the intention of the amendments to the Patent Act in 1987 and 1993 to encourage and foster innovation in the pharmaceutical sector. The Board's Guidelines have historically failed to provide an adequate recognition of the value of innovation in new drug development. A number of the issues under review today threaten to introduce more barriers to investments in innovation in Canada by creating market uncertainty and new impediments to firms to bring products to market at appropriate prices.

EXCESSIVE PRICE GUIDELINE CONSULTATIONS

We share Rx&D's concern that the review of the Excessive Price Guidelines by the Board has become increasingly unfocused over time and now covers too many issues to be reasonably considered at one time. Since the initiation of the consultations 16 months ago, PMPRB has not indicated a clear purpose to its review of the Guidelines and has yet to establish a timeframe for its completion. As the review has proceeded, PMPRB has significantly expanded its scope by adding more and more issues, some of which appear to be more theoretical than practical in nature. In addition to making the consultations unwieldy, this has added a great deal of uncertainty for Bayer and other patentees with respect to the regulatory environment that we will face in the years come.

We support Rx&D's urging that the Board streamline the review of the Guidelines and establish a clear and public timetable with decision points for the completion of this project.

Principles

We note that the Board proposes to add language to the preamble of the Guidelines to this effect:

- The Board's mandate is to ensure that prices charged by patentees for patented medicines sold in Canada are not excessive, thus protecting the interests of consumers.

It is not clear what the Board's purpose is in proposing this change at this time. The mandate of the Board is clearly delineated in Section 83 of the Act, which makes no reference to consumer protection. The Act is intended to encourage innovation by rewarding inventors through the patent system. The Board's role is to ensure that pharmaceutical patentees do not abuse the exclusive rights they receive from a patent by charging excessive prices.

We share Rx&D's view that the proposed reference to consumer protection in the Guidelines is neither helpful nor necessary. However, if the Board opts to proceed with this language, it should be balanced by appropriate references to the objective of promoting and encouraging innovation and investments in the biopharmaceutical sector. This recognizes the fact that consumer protection is fostered not only by non-excessive prices but also by innovation in pharmaceutical treatment; by research and development into new therapies; by the speedy introduction of new medicines; and by access to the widest range of medicines to treat diseases and improve health.

Categories

Bayer shares Rx&D's reservations about the current categories used by the Board as they do not adequately recognized the therapeutic value of new medicines. PMPRB frequently declines to categorize new drugs as breakthroughs or substantial improvements contrary to the use of comparable designations by international bodies and despite evidence that has led Health Canada to assign priority review status.

Bayer views questions relating to categories and the appropriate price tests as inextricably linked. We support Rx&D's proposal in its August 2006 submission to institute an appropriate excessive price test that would remove the need for categories. A price test based on the statutory standard of "excessive" and the factors in the Patent Act would render the categorization of new medicines by the Board unnecessary.

Rx&D's proposal addresses the issue of the appropriate excessive price test for patented medicines and also addresses the concern that the current Guidelines do not adequately recognize the value of incremental innovation in the development of new medicines. It offers a reasonable balance between meeting the objectives of the Act, while allowing a measure of flexibility for patentees to establish prices in response to market conditions. It also addresses the existing problems with the definitions and categories of new medicines used by the Board.

In considering the question of categories, we stand with Rx&D in urging the Board to take the following into account:

- The current Guidelines rely on definitions and criteria for "breakthrough" and "substantial improvement" that are too narrow and are out of step with standards used elsewhere;
- They do not adequately address the incremental improvement offered by many new medicines;
- If the Board adopts an appropriate excessive price test, there is no need for categories; and,
- The Guidelines should not restrict the price of a medicine which offers an improvement in therapeutic effects to the prices of existing medicines.

If the Board decides to establish a working group in this issue, Bayer would welcome the opportunity to participate.

Costs of Making and Marketing

Bayer is pleased that the Board has indicated its intention not to proceed with the initial plan to establish a working group on this issue. Given that the Board has not had to give consideration to subsection 85(2) of the Act to make a determination of excessive pricing, it was not clear why the Board was raising what appears to be a hypothetical issue at this time. We share Rx&D's view that no changes to the Guidelines pertaining to this issue are needed.

Adjusting the Benchmark Price (Re-benching)

Bayer supports Rx&D's position that, in the absence of further information on how the Board intends to review the question of re-benching, we are opposed to any expansion of the current two re-benching criteria given that such an expansion is potentially a source of significant commercial uncertainty.

Any Market

The Board has indicated that stakeholders are of the view that to the extent that any review should be conducted at the level of "any market" rather than on the basis of a national average price, the review should be undertaken only where warranted and on a case by case basis. The Board states that it will be identifying circumstances "where it may be appropriate to review prices in any market."

Bayer shares Rx&D's opposition to any change from the current national ATP definition. The current national definition is the most efficient and preferable definition. The Board has not to date identified any such circumstances and has not demonstrated the need to pursue this issue further. In addition to being inefficient and unjustified, we also believes that any change to consider sub-national markets is inconsistent with the PMPRB's mandate as a Canadian national oversight body making its determinations based upon an examination of Canadian patented medicine pricing relative to the designated international comparator nations set out in the Act.

Conclusion

As noted above, Bayer shares Rx&D's concern over the increasing number of pricing policy issues that have arisen between the PMPRB and pharmaceutical patentees and we are appreciative of the efforts of the Board to attempt to improve ongoing dialogue to help address these issues.

We also share Rx&D's belief that pharmaceutical patentees are not simply a "stakeholder", but that they have considerably more interest in the manner in which the PMPRB carries out its mandate because of its very significant impact on their day to day business activities and long term investment decisions. We welcome the opportunity for further dialogue with the Board and would be pleased to participate in working groups, particularly on the issue of categories and the pricing test.

The number of contentious issues and their potential significance has created considerable uncertainty for patentees. Bayer stands with Rx&D in encouraging the Board to move quickly to consolidate the outstanding issues and establish a work plan to proceed with them. We also encourage the Board to take account of the linkages between the many issues under consideration in this process.

Thank you again for the opportunity to provide comments in the context of the Board's Excessive Pricing Guideline Consultations. Should you require any further information or input, please do not hesitate to contact me.

Sincerely,

Doug Grant
Vice-President, Corporate Affairs
Bayer Inc.
Tel. (416) 246-5001
Fax (416) 240-5292
Email: doug.grant.b@bayer.com