Wyeth Pharmaceuticals
Division of Wyeth-Canada
50 Minthorn Blvd.
Markham, Ontario
L3T 7Y2

Wyeth

October 22nd, 2007

Ms. Sylvie Dupont
Secretary of the Board
Patented Medicines Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON
K1P lCl

Re: Regulations Amending the Patented Medicines Regulations, 1994

Dear Ms. Dupont:

On behalf of Wyeth Canada (Wyeth), I am writing to you with respect to the proposed amendments (Amendments) to the *Patented Medicines Regulations, 1994* announced by the Patented Medicine Prices Review Board (PMPRB) in the Canada Gazette (Part I) on October 6th, 2007.[1]

The Amendments in Context

These latest Amendments are a re-publishing of proposals that first appeared in the Canada Gazette Part 1 on December 31st 2005. In our submission of January 30th, 2006 responding to this publication, Wyeth identified a number of significant concerns that we felt needed to be addressed before the regulations were implemented. Wyeth wishes to acknowledge the PMPRB's initiatives to address some of these matters; specifically, Wyeth is encouraged that the PMPRB has chosen to remove the following proposed amendments: 1) to report proposed price increases in advance of implementation; 2) to include information on patent applications on the Form 1; and, 3) to change the reporting timeline for the Form 2 from 30 days to 15 days. Wyeth is also encouraged with the proposed reduced reporting requirement for initial sale of the patented medicine to the first day's sales only versus the first 30 days sales. Wyeth regards these actions by the

[1] Regulations Amending the Patented Medicines Regulations, 1994, Canada Gazette Part I, October 6th, 2007.

Wyeth Pharmaceuticals
Division of Wyeth-Canada
50 Minthorn Blvd.
Markham, Ontario
L3T 7Y2

Wyeth

PMPRB as very positive, and in the 'spirit of collaboration' with one of its key stakeholders.

While Wyeth notes that significant positive changes have been made from the original proposal, we remain concerned that some of the issues previously identified do not appear to have been given adequate consideration.

Major Jurisdictional and Policy Issues

1. **Reduction in Filing Timelines for Information Respecting the Identity of the Medicine**

> The revised amendments propose that the timeline for provision of this information be changed to the earlier of seven days after the date of issuance of the first NOC in respect of the medicine, or seven days after the date on which the medicine is first offered for sale in Canada.

Wyeth is of the opinion that this amendment places an unreasonable reporting time constraint on patentees, and, in the haste to comply with the required filing deadline, may lead to the filing of incorrect/incomplete forms, with the time-consuming need for subsequent re-filing of corrected data. The PMPRB's position on this filing requirement also seems inconsistent with reporting requirements of other regulatory agencies. For example, under *Food and Drug Regulations*, manufacturers have 15 days from receipt of information to report a serious adverse drug reaction to Health Canada. It seems disproportionate that Health Canada's timeframes with respect to the reporting of serious adverse reactions are more lenient than the PMPRB's proposed filing deadlines related to pricing issues. In the absence of a convincing rationale, the status quo with respect to the filing of Form-1s should be maintained.

2. **Average Price Calculation**

> ...patentees would be required to report the types of benefits deducted in the average price calculation, but not the amounts of each benefit. To further lessen the burden of implementation on patentees, the regulatory amendment respecting identification of specific types of benefits has been changed so that it would come into force on July 1, 2008, and not immediately following publication in the *Canada Gazette*, Part II.

Wyeth Pharmaceuticals
Division of Wyeth-Canada
50 Minthorn Blvd.
Markham, Ontario
L3T 7Y2

Wyeth

Wyeth regards this proposed change as the most serious issue for patentees with respect to these Amendments. Wyeth is of the opinion that this amendment will create an onerous reporting burden at significant cost without creating any material benefits for the PMPRB and/or the Canadian consumer. Wyeth also notes that, should it be necessary for the PMPRB to require the level of additional detailed information sought, the Board has the authority to issue an order, under section 81 of the Act, compelling the patentee to provide the required information. It would seem that isolated requests for additional data can be more efficiently addressed by the Board through telephone calls or emails to the patentees. This new proposed requirement seems contrary to the objectives of the Smart Regulation initiative, which aims to make regulation a source of competitive advantage, not a burden.

Wyeth contends that there is no convincing policy rationale for a change that will definitely increase the regulatory burden for patentees. In addition, the requirement to file such information may, in practice, discourage discounts and programs to the detriment of Canadian patients.

Wyeth appreciates the opportunity to be part of the consultative process and to make this submission to PMPRB. Should you have questions concerning any of the content contained herein, or wish to discuss this document in further detail, please do not hesitate to contact me.

Sincerely,

Jim McIntosh
Manager, Pricing

For Adam Coote
Vice-President, Market Access & Communications