Submission of Wyeth Canada re:
Price Increase for Patented Medicines: Discussion Paper

This submission is on behalf of Wyeth Canada, and is in response to the Patented Medicine Prices Review Board's ("PMPRB") request for comments from interested stakeholders concerning, *Price Increases for Patented Medicines: Discussion Paper*, released March 2005.

Wyeth Canada is a research-based pharmaceutical company with leading therapeutics in the areas of women's health care, cardiovascular diseases, central nervous system disorders, anti-inflammatory disorders, infectious disease, hemophilia, oncology and vaccines. Wyeth's products include biopharmaceutical products that are the result of significant research and development in the biotechnology field.

Since 1883, Wyeth Canada has been making an outstanding, innovative contribution to Canadian healthcare. During the past 5 years, Wyeth has brought to the marketplace several new medicines, including PREVNAR, a breakthrough vaccine indicated for the treatment of pneumococcal infections for children under the age of 2 years, and ENBREL, the most significant advance for the treatment of moderate to severe rheumatoid arthritis in more than 20 years. Wyeth's research and development expenditures, as a percent of total sales, have consistently exceeded the industry average for all patentees, as well as the Rx&D patentees (i.e. for 2003, 13.6%, vs 8.8% and 9.1%, respectively).

Drug Costs and Drug Prices Are Not Synonymous Terms

Canadians are spending increasing sums on healthcare. With the proportion of all healthcare dollars attributed to pharmaceuticals steadily increasing and, since drug costs are easily measured, cost-containment strategies have focused on drug spending. Key factors contributing to rising drug expenditures are changes in drug utilization and drug prices. The aging population, the introduction of therapies to address previously untreatable conditions, and the shift to outpatient care are demonstrated drivers of drug utilization.

However, as acknowledged by PMPRB in the Discussion Paper, the prices of patented medicines in Canada has been stable for the past decade at a level 5% to 12% below the median prices in the 'Basket of 7' countries. In real terms, prices have actually declined because inflation as measured by the cumulative CPI has risen by 21.6% over the same period." [Trends in Drug Price Policies, *Provincial Reimbursement Advisor*, May/2005]. This has occurred in an era where innovation and discovery costs continue to escalate. It is now estimated that the cost of bringing a new compound to the world market is C$1.3 billion. ["The Alchemists", Feb. 21, 1998 and Tufts Centre for the Study of Drug Development, news release, Nov. 30, 2001.]

In the broader context, drug expenditures are a minor component of the total economic burden of illness in Canada, which was estimated to be C$159.4 billion in 1998.[1] This burden incorporates not only direct costs due to disease, such as hospital and physician services and drugs, but also the often hidden indirect costs, including death and lost productivity due to disability. Drug spending continues to represent a small fraction of the Canadian economy: less than 1.6% of GDP in 2002.[2] In

[1] Policy Research Division, Strategic Policy Directorate, Population and Public Health Branch, Health Canada. Economic burden of illness in Canada, 1998. 2002.
[2] Canadian Institute for Health Information. National health expenditure trends, 1975-2002. Ottawa, ON: Canadian Institute for Health Information, 2002.

other words, Canadians spend 1.6 cents of every dollar on all pharmaceuticals. This positions Canada quite reasonably within the 'Basket of 7' countries, with 4 countries spending less (i.e. 1.2 to 1.5 cents) and 3 countries – including the United States – spending more (i.e. 1.7 to 2.0 cents).

PMPRB makes reference, in the Discussion Paper, to the fact that proposed price increases for a significant number of patented medicines have been announced by manufacturers, and questions whether or not Canada is on the verge of price instability. However, no evidence was provided which would indicate that the announced price increases were in violation of current guidelines. The implied suggestion by PMPRB that Canada should consider moving towards an even more restrictive pricing environment seems not only counter-productive but also punitive to the innovative pharmaceutical industry.

It is Wyeth's understanding that the role of PMPRB is to review prices for patented medicines and ensure that these medicines are not sold in Canada at excessive prices. [*Compendium of Guidelines, Policies and Procedures*, Sec. 1 Mandate] Section 85 of the *Patent Act* makes reference to "... the price at which the medicine has been sold" [Patent Act, Sec. 85(1)(a)], reinforcing the role of PMPRB as a reviewer of actual patented drug prices charged.

It is critical that PMPRB balance price policy and consumer protection with the responsibility to foster an environment that encourages investment by the innovative pharmaceutical industry. This means creating a positive investment environment, resulting in continued research and development spending and leading to the creation of new medicines discovered and brought to the marketplace. This benefits the same consumers that PMPRB is mandated to protect.

It is important for policy makers to recognize that in Canada, prices are controlled in two ways. First, at the federal level, the PMPRB reviews the initial price for new products to ensure compliance with its guidelines, and then sets a ceiling for increases indexed to inflation. Second, further controls are then established by the provinces. For example, in Quebec and Ontario, there has been a price freeze on publicly reimbursed medications for over 10 years.

The Frameworks

PMPRB has considered three Frameworks representing different regulatory systems in their Discussion Paper:

Current system where patentees are allowed to take an automatic price increase in a given period up to a predetermined maximum, with price reviews taking place after the fact. [Framework 1]

Patentees would be required to apply to the PMPRB in advance of any price increase, allowing a review of the proposed price increase before it is implemented to ensure that the new price is within the Guidelines. [Framework 2]

Patentees would be required to apply in advance for a price increase and would also be required to provide justification for the proposed increase and the extent of the increase. The PMPRB would make a determination on both the appropriateness of the increase and on the extent of the increase up to a non-excessive maximum. [Framework 3]

Within the context of Framework 1, which is reflective of the existing environment, the burden on patentees to comply with the PMPRB reporting regulations is already significant. Framework 1, while allowing for automatic, non-pre-approved price increases, does so within very clearly defined parameters and guidelines intended to protect consumers against excessive drug prices. PMPRB already has access to many tools, including remedial and punitive powers, to ensure that it achieves its mandate of guaranteeing non-excessive drug prices in Canada.

Wyeth believes that Frameworks 2 & 3 are counterproductive, foster confidentiality concerns, present compliance issues, and are beyond the scope of the Board's existing authority.

Under Frameworks 2 & 3, advanced notification of proposed price increases are required to be submitted to PMPRB by the patentee, with increasing degrees of 'pre-approvals' necessary before such price increases can be implemented. Section 4(1)(e) of the *Patented Medicines Regulations, 1994*, stipulates that the patentee must report "... the quantity of medicine sold and either the average price per package or net revenues ... (by) dosage form, strength and package size". [Patented Medicines Regulations, Sec. 4(1)(e)] Section 4(4) further defines average selling price to be "... actual price after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature". [Patented Medicines Regulations, Sec. 4(4)] Based upon these definitions, Wyeth contends that it would be ineffective and inefficient utilization of the Board's resources to review 'proposed prices', as these prices may not be reflective of the actual average selling prices, as defined within the guidelines, and which form the basis of assessing price compliance with the Board's non-excessive pricing criteria.

For commercially marketed drugs, it is an absolute necessity that price strategy be carefully guarded, due to the very competitive nature of the pharmaceutical industry. While there is no evidence to suggest prior breaches of confidentiality by the Board or its staff, Wyeth is concerned that, with the significant increase in collaborative initiatives between the Board and the federal/provincial/territorial health ministries, as well as the more extensive use of external expert consultants, there is a heightened risk that advanced notification of pricing strategy shared with PMPRB may inadvertently find its way into the public domain, resulting in the patentee being placed in an untenable and disadvantageous competitive position.

Wyeth further believes that Frameworks 2 & 3 are impractical from a compliance perspective. The assessment of competitive intelligence and market conditions are key components in any price increase scenario. Typically, such activities are being conducted virtually up to the time any price increases are finalized, and, given the competitive pharmaceutical market, actual price increase are not likely to be known sufficiently in advance of implementation to allow for their timely review and approval by PMPRB.

Wyeth questions the value to be realized by Frameworks 2 & 3, resulting in significant increase in reporting requirement burden placed upon the patentee as well as the additional reviewing workload placed upon Board staff. The existing requirements are for semi-annual submissions and reviews, and anything more frequent than this would seem to be of very questionable value for either the patentee or the Board.

<u>Wyeth Submits the Following Comments to The Questions Posed in the Discussion Paper:</u>

1) Should the PMPRB's Guidelines continue to allow automatic (i.e. without prior approval) price increases?

Wyeth believes there is no justification, nor legal authority, requiring patentees to secure PMPRB's advance approval before implementing price increases. Further, it is Wyeth's contention that the overall limitations imposed by the PMPRB guidelines preclude the implementation of excessive price increases. Wyeth would also suggest that, with the prevailing cost-containment attitudes of provincial governments, and their significant impact on the reimbursement status of drugs, price increases are anything but automatic.

Unlike in Europe, where price controls only apply to drugs reimbursed by government health plans, Canadian prices of patented medicines are subject to reviews by the PMPRB, separate reimbursement reviews by each provincial and federal plan, and provincial pricing restrictions. While PMPRB points to cost-containment initiatives implemented in many countries, and suggests that these may be an appropriate avenues to be followed by Canada, it should also be noted that the

path to unrestricted reimbursement for innovative new drugs is much less direct, and less likely to occur, in Canada than in many of these same countries, i.e. Germany and United Kingdom.

2) Are there considerations other than, or in addition to, the CPI that should be used to review price increases?

Wyeth believes that the full provisions of Sec. 85(1) should be taken into consideration when reviewing price increases. In addition to the CPI, Sec. 85(1) identifies the following considerations to be included in the review process: a) the price at which the patented medicine has been sold in the relevant market; b) the prices of other medicines in the same therapeutic class which are sold in the relevant market; c) the price at which the patented medicine and other medicines in the same therapeutic class are sold in other countries; and, d) other factors specified in any regulations made for the purpose of reviewing for excessive prices.

3) How often should price increases occur? (e.g. every year, once every 3 – 5 years, only after a certain introductory period, when justified)

It is Wyeth's opinion that the timing and frequency of implementation of price increases are strategic decisions that are in the purview of the Company. In addition, Wyeth contends that there are sufficient market place factors that govern the frequency of implementing price increases. It should also be noted that there are no provisions within the Patent Act that would extend PMPRB's authority to these matters.

4) If justification is required, what criteria should be considered?

There is no current legal requirement in either the Patent Act or the Regulations requiring patentees to provide advanced notification of price increases to PMPRB. In fact, PMPRB's mandate, as noted previously, is to review "the price at which the medicine is being or has been sold", not to regulate or obtain advance information on potential future prices. Further, Wyeth believes that Frameworks 2 & 3 extend PMPRB's authority well beyond their mandate of ensuring that the prices of patented medicines in Canada are not excessive.

As noted previously, it is Wyeth's contention that advance approval from PMPRB to implement price increases is not necessary; accordingly, justification of price increases should only be required in those situations where the Board has reason to believe the actual average selling prices of a specific drug SKU is excessive. In these cases, there are well established policies and procedures available to the Board to investigate such suspected excessive prices, as well as multiple remedies to rectify the situation, if it is determined that the prices are in non-compliance with PMPRB guidelines.

5) Given that the CPI is established in the Patent Act as a factor to be considered by the PMPRB, do you have any comments on its appropriate application in future Guidelines?

The CPI is an appropriate index to establishing the benchmark for price increases. The CPI provides a broad measure of the cost of living in Canada. While there are other ways to measure price changes, the CPI is the most important indicator because of its widespread use. Inflationary pressures do not escape the pharmaceutical industry. As such, the year-over-year CPI provides due consideration and equity across sectors.

Conclusion

Research-based pharmaceuticals entail sizable fixed costs for research and development (R&D), which must be recouped if R&D is to continue. The purpose of patents is to protect intellectual property rights and to sustain future R&D investment. Thus, pharmaceutical R&D is a "global joint" cost – that is, once incurred, it can benefit consumers worldwide. The issue is how should the joint cost of R&D be allocated across countries? The Canadian system of price regulation, reimbursement, and competition have contributed to the relative disparity between Canadian and

US prices, after accounting for exchange-rate impact. The economic answer to this question is that if the objective is to maximize social welfare, then the global joint costs should be recouped through price markups that differ based on country income levels. Thus, price differentials that are related to income would be consistent with both economic efficiency and equity.

It is Wyeth's opinion that pricing in the pharmaceutical industry needs less, not more, regulation. While recognizing PMPRB's mandate to protect consumers' from excessive drug prices, Wyeth suggests that it is equally important that the Board recognize and balance its responsibilities to ensuring an investment climate which encourages and rewards innovative medical research and development. The implied undertone to the Discussion Paper suggests that the Board, while not making any specific proposals concerning price increases, supports a move to tighter controls in this area. Wyeth views the imposition of additional pricing regulations as unnecessary, excessive, and a further erosion of the balance between investment and consumer protection.

In closing, Wyeth Canada appreciates the opportunity to comment on the Discussion Paper issued by the PMPRB and looks forward to receiving the results from this consultation.