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Wyeth

April 27, 2009

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

Dear Dr.Benoit,

As a leading pharmaceutical manufacturer in Canada, Wyeth Pharmaceuticals has actively participated in PMPRB's initiatives during the past 3+ years to engage stakeholders in the process of proposing and assessing amendments to the *Excessive Price Guidelines*. Wyeth is pleased to continue its involvement in these discussions.

The attached document is Wyeth's response to the *Notice and Comments and Draft Revised Excessive Price Guidelines* package released March 25, 2009.

Thank you for the opportunity to comment on this important issue.

Sincerely,

Adam Coote
Vice-President, Market Access and Communications
Wyeth Canada

WYETH'S RESPONSE TO THE

PATENTED MEDICINE PRICES REVIEW BOARD'S

NOTICE AND COMMENTS PACKAGE

"Draft Revised Excessive Price Guidelines"

[Released for comments March 25, 2009]

INTRODUCTION

Since the beginning of the Patented Medicine Prices Review Board (PMPRB)'s consultation process with stakeholders in 2006 concerning potential revisions to the *Excessive Price Guidelines* (EPGs), Wyeth has been an active participant in these very important discussions. As a patentee, Wyeth will be directly and significantly impacted by any revisions to the EPGs, and, therefore, appreciates this latest opportunity to continue to provide comments on the proposed amendments.

As a member of Canada's Research-Based Pharmaceutical Companies (Rx&D) and BIOTECanada, Wyeth is familiar with, and fully supportive of, their formal industry responses to this latest PMPRB request for comments on the Notice and Comment package, *Draft Revised Excessive Price Guidelines* (N+C), released March 25, 2009.

This submission provides Wyeth's response to selected sections of the N+C which are of particular relevance to our Company.

Before addressing the specific technical issues and their implementation, Wyeth would like to convey its concern with, and opposition to, the proposed amendment to the PMPRB's mandate. The mandate given to the PMPRB by Parliament is to ensure that prices in Canada are not excessive. The light under which the mandate is interpreted depends greatly on the experience of the people tasked at a specific moment in time to implement the rules and regulations that flow from this original mandate.

The proposed amendments, based on discussions that occurred at the time of creation of the PMPRB, fail to reflect the balance that was sought at the time between ensuring that Canadians have access to drugs for which prices are not excessive and the need to foster a strong innovative industry in Canada. By proposing a one-sided interpretation to the mandate by adding "consistent with the interest of consumers and the Canadian Health Care system", the PMPRB is selective and introduces a bias in the mandate. The phrasing chosen may also have a detrimental impact on Canada's capacity to ensure that the products with the non-excessive prices remain in Canada for the use of Canadians since there is no qualification of "consumers" indicating that they are in Canada.

Though Wyeth believes that the mandate should only be amended by Parliament, if the mandate is to be amended, the following should also be added "…consistent with the interest of

consumers in Canada and also consistent with the country's intent of fostering a strong innovative sector in Canada".

By doing this, the PMPRB would recognize that it does also have a mandate to ensure that innovation investments continue in Canada as indicated by the "merest slender thread" of the fact it reports annually on R&D investments by patentees in Canada and has done so since its creation.

Technical Issues

Based upon a comprehensive review of the March 25th, 2009 N+C document, Wyeth continues to have concerns with respect to several of the proposed amendments to the EPGs, including:

- The increased regulatory burden and reporting complexity to manage prices in any market;
- The time line for implementation of the amended guidelines and grandfathering provisions;
- The introductory price review methodologies;
- The publication of international & Canadian pricing information;
- The methodology for offsetting excess revenues.

The following comments will highlight Wyeth's specific concerns with respect to each of the aforementioned issues.

ISSUE: The increased regulatory burden and reporting complexity to manage prices in any market

Wyeth is concerned that the proposed revisions to the EPGs will result in increased scrutiny/price control being imposed on the price of patented medicines. While the PMPRB acknowledges that their mandate does not grant them price control authority, the proposed amendments seem to be moving them in this very direction. Further, Wyeth continues to believe that the implementation of the proposed amendments to the EPGs will add significant burden not only to patentees, but also to the PMPRB staff. While the PMPRB has attempted, in this latest draft revisions to the EPGs, to address some of the increased reporting burden concerns expressed by Wyeth and many other stakeholders throughout this consultation process, the uncertainty to the patentee that a much broader 'in any market' review could be triggered at any time mandates that the patentee proactively monitor and manage prices in all 4 classes of customers across all 13 provinces/territories.

The requirements associated with the proposed DIP methodology is linked with the 'in any market' review issue and is another example how the new EPGs will increase the workload of both the patentee and the PMPRB staff. The whole approach for patentees to manage their contract business will have to be re-assessed; relationships with contractual partners will become increasingly complex, as patentees will demand more detailed information from these business

partners in order to satisfy the patentee's PMPRB reporting obligations. The PMPRB staff will face the difficult task of identifying excess revenues at multiple market levels without the aid of clearly defined criteria as a guide. The absence of tested methodologies to calculate excess revenues will also create increased workload, uncertainty and frustration for both patentees and the PMPRB staff.

With all of the increased regulatory burden and reporting complexities that are inherent in the proposed amendments to the EPGs, one must ask the questions: What are the benefits, to Canadian consumers, the PMPRB and patentees that justify these changes? How will these changes enable the PMPRB to carry out its mandate more efficiently and effectively, that is, ensuring that prices of patented medicines in Canada are not excessive? Will the proposed changes create additional price control mechanisms and will these changes interfere or misalign with provincial health care systems? Will the proposed changes result in a significantly higher rate of compliance? Wyeth believes that a higher rate of compliance is very unlikely, since, as the PMPRB's own documents and publications attest, the price of most patented medicines are in compliance with the current EPGs.

Wyeth strongly urges the PMPRB to reassess it proposal to conduct price reviews 'in any market'. As expressed above, it is Wyeth's opinion that the consequences of implementing such price reviews, as measured by additional regulatory burden, reporting complexities and pricing uncertainties, far outweigh any benefits which may accrue, as measured by improved compliance rates and reduced investigations.

ISSUE: The time line for implementation of the amended guidelines

The PMPRB has targeted July 1st, 2009 as the implementation date for the revised EPGs. Wyeth believes that to move forward and adhere to the July 1st date for implementing the proposed changes is counterproductive and, perhaps, short-sighted. There remain several key issues which have yet to be adequately addressed and resolved, including the implications arising from the outstanding judicial review proceedings examining the PMPRB's jurisdiction regarding the reporting of benefits, which is schedule to be heard in Federal Court in mid-June. Many technical elements must yet be developed to facilitate transition from the existing EPGs to the amended EPGs, for patentees to fully understand how to price their patented medicines to ensure conformance with the new EPGs, and for the PMPRB staff to understand and correctly apply the new EPGs to facilitate the achievement of the PMPRB's mandate of ensuring the Canadian prices of patented medicines are not excessive.

Wyeth encourages the PMPRB to reconsider its targeted implementation date, and consider deferring the implementation of the new EPGs indefinitely until all key issues have been resolved. A tremendous amount of time, effort and energy have been invested by all parties during the consultation process; it would be a disservice to all to rush through the remaining phases of this process, without ensuring that all the technical implementation issues have been fully resolved, and get a final product that satisfies none of the stakeholders.

Furthermore, transitional provisions must be provided to grandfather existing products that have been reviewed and priced already under the current Guidelines, as well as products that are currently under review.

ISSUE: The introductory review methodologies

Wyeth has a number of concerns surrounding the proposed revisions to the methodology to be employed during the introductory review of a new patented medicine.

The acceptance by the PMPRB of the recommendation by the Working Group on Therapeutic Improvement (WGTI) to expand the recognition of levels of therapeutic improvement to include moderate improvement is a positive step forward, as is the PMPRB's acknowledgement that there is an appropriate role for considering secondary factors when assessing the level of therapeutic improvement for the new patented medicine. Wyeth does, however, find it perplexing that the PMPRB, while appearing to heed the position of WGTI that the Human Drug Advisory Panel (HDAP) should have final responsibility for determining the level of therapeutic improvement of any new patented medicine (Report of WGTI, April 2008, sec. 3.11 & 4.8; EPGs, Part III, Chapter 1, 7.2 – 7.4), seemingly has predetermined the exercise of HDAP's independent review by declaring that "… secondary factors do not carry sufficient weight to move the level of therapeutic improvement from "moderate' to "substantial improvement" (EPGs, pg iii). Wyeth encourages the PMPRB to re-think its position on the role of secondary factors in the assessment of therapeutic improvement, and allow HDAP unrestricted latitude to assign the appropriate level of therapeutic improvement on the basis of all of the evidence examined.

For purposes of conducting the introductory price test of a new patented medicine for which no direct comparator can be identified, the PMPRB is proposing to use the lowest price of a "superior" class of drugs, which, depending on the therapeutic class, may or may not include generic drugs. This proposed approach is disconcerting from two aspects: a) Wyeth believes that the identification of "superior" products is outside the scope of the PMPRB's jurisdiction; 2) it creates an unacceptable level of price uncertainty for the patentee when assessing the appropriate price at which a new medicine can be brought to the marketplace as a commercial success.

With respect to the International Therapeutic Class Comparison (ITCC) test, Wyeth continues to be of the opinion that the inclusion of any generic comparator in the ITCC is inappropriate. By using generic comparators, the PMPRB does not recognize "innovation" which goes against the underpinning notion of intellectual property/patents of "patented products". Wyeth is also concerned that the inclusion of generic prices will significantly skew the results of the test. Because of differing generic market dynamics within the PMPRB's reference countries, Wyeth believes that the inclusion of any generics in the ITCC test would significantly and artificially skew the test results. To ensure that the ITCC component of the price review test is robust and meaningful, Wyeth encourages the PMPRB to remove from the guidelines all reference to generics in the ITCC test.

ISSUE: The publication of international & Canadian pricing information

Wyeth is concerned by the expressed intent of the PMPRB to publish, without patentees consent, international price information submitted by patentees in Block 5 of Form 2 of the semi-annual report of prices and net revenues.

First, this proposal is outside the jurisdiction of the PMPRB, in that it is a breach of the statutory privilege in section 87 of the Patent Act. It is no answer to the absolute privilege of section 87 to say that the information sought is specified in the Patented Medicines Regulations to be publicly-available. Section 87 protects *all* information provided to the PMPRB under section 80, 81 or 82. There is no exemption for publicly-available information.

Second, the proposal is misconceived from the standpoint of policy. While in theory the price information provided by patentees in Block 5 should come from publicly available sources, various market conditions make this impractical in practice. For example, obtaining ex-factory prices for particular classes of customers, i.e. hospitals, is not possible in some markets. In a spirit of cooperation and helpfulness, it has been Wyeth's practice to submit confidential internal ex-factory pricing information in such cases. The publication of such information by the PMPRB without express written consent from the patentee could adversely compromise Wyeth's pricing practices in such markets. Even if the PMPRB had jurisdiction, a proposal to publish Block 5 information will inevitably result in patentees providing only publicly available information in strict accordance with the requirements of the regulations.

Third, Wyeth fails to comprehend what value the PMPRB would see in making such information publicly available and how this would assist it to carry out its mandate of ensuring Canadian prices are not excessive.

Wyeth recommends that the PMPRB remove Part I, 9.2 from the EPGs, and revert back to the current practice of securing the patentees consent before making any submitted price information publicly available. Should the PMPRB choose to move forward with this proposed amendment, Wyeth will be forced to adhere to the letter of the requirement of only reporting publicly available foreign pricing information on Form 2 Block 5.

ISSUE: The methodology for offsetting excess revenues

The current EPGs permit patentees the option to 'refund' excess revenues below the investigation triggers which were generated in a prior year by either not taking an allowable price increase, or taking less than the maximum price increase allowed. Under the proposed revisions to the EPGs, (Part II, 7.2), the PMPRB is eliminating this as a remedial option available to patentees.

As justification for this revision, the PMPRB states "… in accordance with Section 83 of the Act an actual price reduction is **necessary** [*emphasis added*]… to offset the revenue" (N+C, Part II, Section 7.2). An examination of Section 83 of the Act reveals no such evidence mandating an

actual price reduction; in fact, every reference to actions available to the Board to address excess revenue situations use the much more flexible phrase, "… the Board may [*emphasis added*], by order, direct the patentee …".

The PMPRB rightfully asserts that the generation of excess revenues reflects the fact that some customers paid prices which were non-compliant with EPGs. Wyeth agrees with this assertion, that some form of remedial action is appropriate, and contends that the current practice of deferring part/all of an otherwise allowable price increase in a subsequent year works effectively: the customer benefits from lower future prices due to the deferral of all/part of any planned price increase; the excess revenues are eliminated, and effectively returned to customers to offset prior 'overpayments'; any additional administrative burden on the patentee to manage a price reduction has been minimized; and the PMPRB's frequently expressed position during these consultations that the changes to the guidelines would allow for greater pricing flexibility for patentees would be achieved.

Wyeth believes that Part II, 7.2 is a needlessly punitive change, and urges the removal of this provision.

CONCLUDING COMMENTS

In summary, the key messages Wyeth wishes to bring forward in this submission are:

1. The PMPRB mandate should not be amended without express agreement by Parliament and if it is it should represent a balanced view of the various interests that have led to its creation.

2. The implementation of the proposed revisions to the EPGs will increase scrutiny/price control over the price of patented medicines without offering additional value to Canadian consumers. The PMPRB themselves acknowledges that they have neither the mandate nor the authority to be engaged in price control activities. As a practical concern, the proposed amendments will add a significant burden to patentees, in terms of time and resources to gather and compile the additional data required to be reported, as well as more extensive monitoring activities of prices and sales data in multiple markets to ensure non-excessive pricing and full compliance with the amended EPGs. Wyeth continues to be concerned that the reality of how the proposed changes to the EPGs will adversely impact patentees is not being adequately taken into account;

3. There are still several key issues to be resolved, including resolution of the Judicial Review examining the PMPRB's jurisdiction regarding the reporting of benefits. To move forward with implementation for July 1st, 2009 would seem to be counterproductive, and the final EPGs implemented may be unsatisfactory to all stakeholders. An additional transitional period needs to be provided as well as appropriate grandfathering provisions for products currently under review and/or already priced in accordance with the current Guidelines;

4. The PMPRB is encouraged to acknowledge that HDAP has the exclusive mandate to assess the level of therapeutic improvement, including assigning a substantial

improvement classification based upon secondary factors, should the supporting evidence deem such a classification appropriate;

5. It is beyond the scope of the PMPRB to identify and compare a new patented medicine to products it deems to be of "superior" therapeutic value. If there are no direct therapeutic class comparators for a new patented medicine being reviewed, the provisions of Part III, Chapter 2, Section 2.10 provide the appropriate price test methodology.;

6. All generic drugs should be exclude from the ITCC test; any references to such inclusions contained within the proposed EPGs should be removed (i.e. Schedule 7, 2.2);

7. The Guidelines cannot contradict or prevail over provisions of the Patent Act from which the PMPRB derives its jurisdiction. The PMPRB must respect the confidentiality of patentees' pricing information submitted to them (i.e. on Form 2, Block 5) and comply with the statutory privilege provided in section 87 of the Patent Act. Such information should only be made publicly available by the PMPRB if it has secured the patentees consent to publish the information;

8. The PMPRB should restore the current remedial option that permits patentees to offset excess revenues generated by deferring all/part of the allowable price increases in a subsequent year by removing Part II, 7.2 from the proposed amendments.

Wyeth appreciates the opportunity to continue to be engaged in these discussions to revise the EPGs.