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Pfizer Canada Inc.

Via fax and email

August 24, 2006

Sylvie Dupont
Secretary of the Board
Patented Medicines Prices Review Board, (PMPRB)
P.O. Box L40, Standard Life Centre
333 Laurier Avenue West, 14th floor
Ottawa, Ontario
K1P 1C1

Dear Ms. Dupont;

Please see attached Pfizer Canada's submission in response to the *Discussion Guide for the Consultations on the Board's Excessive Price Guidelines* issued by the PMPRB in May 2006. Pfizer appreciates the opportunity to comment on the guide and, further, looks forward to participating in later phases of the consultation, including, but not limited to, taking part in the public meeting scheduled for November 8, 2006 in Montreal.

In reviewing this submission, please note that the Pfizer Canada remarks should be viewed as a supplement to the input provided by Canada's Research-Based Pharmaceutical Companies (Rx&D) of which Pfizer Canada Inc. is a member. This submission is intended to support and expand on those ideas in a manner reflecting the experience of an organization that is required to comply operationally with the Board's guidelines.

Overall, patent holders have priced their medications in a responsible manner during the almost two decades since the Board's creation. Given this, the Board should use this opportunity to consult stakeholders on how it can reduce its regulatory burden and streamline current processes while still achieving its goal of preventing excessive pricing of patented medicines. Pfizer's submission, along with that of Rx&D, provides specifics on how this can be accomplished. In addition, taking this approach would also assist the Board accomplishing its sometimes overlooked mandate of encouraging R&D investment in Canada.

Thank you again for the opportunity to comment on these important questions. Please do not hesitate to contact the undersigned for further clarification or perspective regarding the above.

Yours sincerely,

G. Lallemand

Guy Lallemand
Vice President – Government & Stakeholder Relations

Pfizer Canada Response to the PMPRB's Discussion Guide for the Consultations on the Board's Excessive Price Guidelines

August 2006

Pfizer Canada welcomes the opportunity to provide comments to the Patented Medicines Prices Review Board (PMPRB) with respect to the issues raised in the May 2006 *Discussion Guide for the Consultations on the Board´s Excessive Price Guidelines*. This commentary is presented in two parts. The first section outlines general observations related to the PMPRB's current consultation initiative and its relevance in the current environment. The second section provides some direct responses to the questions raised in the discussion guide.

In reviewing this submission, please note that Pfizer Canada's remarks should be viewed as a supplement to the input provided by Canada's Research-Based Pharmaceutical Companies (Rx&D) of which Pfizer Canada Inc. is a member. This submission is intended to support and expand on those ideas in a manner reflecting the experience of an organization that is required to comply operationally with the Board's guidelines.

Additionally, it should be noted that, while Pfizer Canada supported the agreement which led to the creation of the PMPRB, it does not believe generally that significant regulatory interventions in the marketplace represent good public policy.[1] While Pfizer respects the responsibility of governments to protect the public interest through the creation of laws and regulations which impose common rules of practice among competing interests, those powers should be used very carefully. As much as possible, legitimate commerce should be permitted to go on within a restrained and austere regulatory framework which supports and encourages vibrant economic growth and innovation. It is through that lens that that the following submission is being made.

General Observations

According to the discussion guide, the initial impetus for the current review was the PMPRB's concern that a spate of price increase announcements made by major brand name pharmaceutical companies in 2003 and 2004 would lead to the breakdown of the pricing stability that had been achieved after the passage of *Patent Act* amendments in the late 1980s. That concern prompted a consultation process conducted during 2005. The conclusions, as the current discussion guide points out, suggested that stakeholders did not feel that price increases were a major issue for them. In addition, the Board had concluded before the discussion guide was issued that the announced price increases were compliant with its regulations.[2] Although these findings indicated that Canada continues to experience patented pharmaceutical price stability, the Board concluded that some additional issues raised during the 2005 consultations still need to be addressed. Hence, this latest consultation process was undertaken.

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[1] However, under the circumstance at the time, Pfizer, along with its industry partners recognized the political need to demonstrate to the Canadian public that the market exclusivity that derives from the reliance on patent protection would not be used in manner that would be abusive or perceived to be so, by creating a mechanism to ensure that product pricing of patented medicines would not be excessive.

[2] In its 2005 Annual Report, the PMPRB notes that average price increases in 2004 and 2005 were less than one per cent, and significantly below the concurrent CPI increases during the same timeframe.

Given the lack of significant stakeholder concern about the threat of potential price increases, and that recent increases have been in full compliance with PMPRB regulations, Pfizer Canada questions the advisability of the current round of consultations. In particular, there appears to be little public policy rationale for a process that could lead to further price regulation in a manner that continues an emerging trend towards extending the Board's original mandate. After almost twenty years of experience, it is clear that innovative pharmaceutical companies have largely refrained from abusing their patent rights through the charging of excessive prices.

This is especially true when the PMPRB's definition of excessive pricing is considered. In general, the PMPRB defines excessive pricing as being above the international median or above a long-standing range of prices in mature therapeutic classes. As a result, the Board's regulations deem prices excessive which are actually entrenched within the norm (e.g. at the international median). This would be different than most definitions of excessive which would imply pricing significantly above what would be considered the norm. In addition, the PMPRB's own data demonstrate that, on average, Canadian prices of patented medicines have remained consistently below the international median and annual increases have been well below the Consumer Price Index (CPI) since the Board was established.

Further support for the absence of excessive pricing is demonstrated by pricing trends for Category 3 medications. Between 1999 and 2004, with the exception of the year 2000, more than 80 per cent of new Category 3 products introduced by patentees have been priced below the maximum non-excessive price (MNE) defined by the Board. At least 30 per cent in each year have been priced at less than the maximum by 25% or more. A May 2003 article was more precise about this practice, noting that most new products introduced are priced, on average, more than 10 per cent below the amount that would be permitted by the Board's guidelines.[3] Taken together, these facts indicate a definitive pattern of responsible pricing practices by industry.

Given the responsible pricing of patented medicines over almost two decades, the Board should use this opportunity to consult stakeholders on how it can reduce its regulatory burden and streamline current processes for patent holders and other stakeholders, while still achieving its goal of preventing excessive pricing of patented medicines. There is significant evidence that shows real benefits for patients and the Canadian economy that could accrue from such an approach. For example, an article that appeared in *Health Economics* correlated high levels of price regulation with a lower likelihood of the availability of innovative medications. The paper also showed that patients living in countries with a less stringent regulatory oversight of pricing gained quicker access to new medications than in nations with more regulatory control.[4]

The current consultations also offer the PMPRB an opportunity to engage stakeholders in exploring an often under-represented component of its mandate – to encourage innovation and R&D investment in Canada. In recent years, this part of its mandate has been limited to annual reporting on R&D spending and substantially over-shadowed by

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[3] Neale, Susan and Palmer, Neil, *Who Really Controls Pharmaceutical Pricing In Canada?,* Provincial Reimbursement Advisor, IMS Health Canada, May 2003, pp. 42-47.

[4] Danzon, Patricia, Wang, Liang and Wang, Y. Richard, *The Impact of Price Regulation on the Launch Delay of New Drugs – Evidence From Twenty-five Major Markets in the 1990's,* Health Economics, Vol. 14, September 2004, pp. 269 - 292

its primary focus on regulating the price of patented medicines. As indicated in the Rx&D submission, there are a number of ways to integrate the notion of "encouraging innovation" into the Board's price review process. Broadly speaking, the best way to do that is to avoid intervening in the marketplace unless there is evidence of truly "excessive" pricing. For example, the Board should

- Consider moving to an oversight model based on the PMPRB's current practice related to animal health products wherein the Board's interventions are prompted through a public complaints mechanism only;
- End the practice of regulating and requiring patent holders to file reports related to any products that are subject to direct generic competition. In this scenario, there is no potential for excessively pricing a medication as the availability of a generic alternative means that a competitively priced Health Canada approved substitute exists in Canada and is widely available in the marketplace;
- Refrain from reviewing prices of products that are established through negotiated contracts with government agencies, (such as vaccines and blood products) given that those negotiations are an effective means of keeping prices in check; and
- End the regulation and requirement for patent holders to file reports related to medications offered over-the-counter. By definition, these medications are subject to intense consumer-controlled price restraint mechanisms.

Given the above, Pfizer strongly recommends that the PMPRB use this round of stakeholder consultations to discuss how it can encourage both elements of its mandate equally by streamlining its regulatory function such that only truly abusive pricing practices are subject to its oversight. It is in this spirit that the next section of this submission, (i.e., responding to the questions raised in the discussion guide) is offered.

Responses to Discussion Guide Questions

Issue 1 – Categorization

Q1 - Are the new, patented drug categories and their definitions appropriate?

As outlined in greater detail below the PMPRB's current categorization practices are not justified within its current mandate of preventing excessive pricing and require significant reform.

Based on Pfizer's experience, the current practices related to the application of Category 2 and 3 to new innovative medicines have been too restrictive to adequately recognize pharmaceutical innovation. Regarding Category 2, the PMPRB's definition of breakthrough or substantial improvement is too limited and not in alignment with that of Health Canada or the United States Food and Drug Agency (FDA). According to a 2004 Bain and Company study sponsored by Pfizer Canada, both agencies have recognized significantly more medications as breakthroughs or substantial improvements than the PMPRB.[5] The misalignment of the PMPRB's definition of breakthrough or substantial improvement with that of Health Canada, the Common Drug Review, and some provincial drug

[5] Bain & Company, Inc., *The Economic and Health Impact on Canada of Pharmaceutical Regulations and Pricing Policy*, September 2004, p. 31.

programs causes confusion for Canadians as it has the potential to slow and/or delay Canadians' access to needed innovations.

Some Pfizer-specific examples of medicines that were relegated by the PMPRB to the status of "moderate, little or no improvement" when compared with existing therapies include

- Viagra, the first oral treatment for erectile dysfunction, (the alternative options available at the time of its launch included inserting an ovule or giving oneself a needle directly in the penis)
- Lyrica, the only medication specifically indicated for the treatment of neuropathic pain associated with diabetes peripheral neuropathy (DPN) and post-herpatic neuralgia (PHN) in Canada
- Somavert, a treatment of last resort for acromegaly patients who are resistant to all other treatment alternatives, and
- Vfend, a new anti-fungal agent showing a major improvement in efficacy and survival in the treatment of invasive aspergillosis (IA) compared to the conventional amphotericin B, then considered the gold standard treatment of IA

In some cases, such as the situation with Vfend and Somavert, the Board determined that the new medicine was not a breakthrough, yet was unable to identify any comparators against which to conduct the Therapeutic Class Comparison (TCC) price test, which typically is used for category 3 medicines. The lack of comparators would indicate that the medication is a highly novel one deserving of Category 2 status.

Most importantly, it is not appropriate for the PMPRB to categorize medicines beyond a determination that some new entrants are simply new strengths and dosage forms of existing medicines. An example of this difficulty is demonstrated by the fact that some category 3 medications have actually achieved an MNE price higher than they would have as category 2 medications.
Any assessment of how much of an improvement one medication is when compared to others is fraught with complexity and subject to a great deal of arbitrary judgment, especially in the early stages following the launch of a new medication. These questions are more properly addressed through a rigorous, but fair, reimbursement review process subsequent to a price being set.

Given that the Board's mandate is to protect the public against potential abuse of patent rights through excessive pricing limits, there is no justification for it to make distinctions about the relative effectiveness of a given medicine versus alternatives. The only question that the Board staff should be trying to address is if the price proposed for a new innovation is excessive based on a review of the factors outlined in Section 85(1) of the *Patent Act*.

The elimination of categories, (other than identifying line extensions versus new innovative medications) would offer several advantages. It would permit the Board to rely on simple price tests, with limited scope, in order to assess how excessive a proposed price might be. This would eliminate the need to determine how an innovative new medicine fits within the therapeutic mix. It

would allow the Human Drug Advisory Panel and all the associated time and effort to support the panelists' work to be disbanded without compromising the Board's excessive pricing mandate. Finally, it would also recognize that the practice of medicine is based on the individual. For example, later entrants into an established category of medications may be a breakthrough for a patient for whom the earlier entrants did not provide a benefit.

Q2 - Is it important to distinguish a medicine that offers "moderate therapeutic improvement" from a medicine that provides "little or no therapeutic improvement?" If yes, why is it important? If not, why not?

No. Consistent with the response above, Pfizer recommends that the categorization of medicines based on an assessment of relative effectiveness be rejected as a means of determining the appropriateness of a proposed price. However, if the current categorization system is to be retained, then Pfizer encourages the Board to find the means to recognize and reward innovators for the value associated with genuine therapeutic improvements, even if they are moderate.

Q3 - If the answer to question 2 above is yes, on what basis would a new medicine that offers "moderate therapeutic improvement" be distinguished from a new medicine that provides "little or no therapeutic improvement"?

See above.

<u>Issue 2 – Excessive Price Tests</u>

Q1 - *Are the price tests currently used to review the prices of new medicines in the various categories appropriate for that category? Why? Why not? If not, how could these tests be amended to improve their appropriateness?*

As stated above, Pfizer recommends the elimination of categorization. In addition, the PMPRB should adopt a much more streamlined approach to determining whether a proposed price is excessive (as addressed in the Rx&D submission) by reducing the number of price tests. Moreover, Pfizer agrees with Rx&D that the Board has interpreted the term "excessive" too liberally and concurs with the notion that a determination of excessive price should be made only when proposed prices are clearly out-of-line with reason.

The data presented in the discussion guide support this proposal in that it demonstrates that the current price tests are not adequate to ensure that the, presumably more innovative, Category 2 medicines are able to achieve any sort of price premium over Category 3 medications. In fact, the current price test used for Category 3 medicines can be more advantageous to innovators from a pricing perspective than the Median International Price test, used primarily to address breakthroughs or substantial improvements. This makes it clear that attempting to categorize medicines and then, determine which tests to use, is a questionable use of resources.

However, as some might interpret the data to suggest that the PMPRB should be more stringent in regulating the allowable prices for Category 3 products, it is

important to remember that the PMPRB does not set prices, but simply identifies an MNE price. Patent holders are free to charge less, and the evidence confirms that they often do. In addition, buyers already have been successful using non-PMPRB related mechanisms to keep prices below the level that a strict interpretation of the PMPRB guidelines would allow. This suggests that, while the PMPRB may have played a role in moderating pharmaceutical prices, the realities of the marketplace represent an effective way to keep suppliers' prices in check.

It is important to note that the PMPRB's current price regulation process actually discourages the market from operating as effectively as it might. Currently, suppliers may be reluctant to reduce prices to meet a customer's demands given that reductions cascade such that the price at which the medication can be sold elsewhere is limited. Instead the PMPRB might consider that consumer interest can be protected through the setting of an MNE price nationally and market dynamics can be relied upon to ensure that individual buyers obtain the best possible price that they can negotiate.

Q2 - If you think that medicines that offer "moderate therapeutic improvement" should be distinguished from medicines that provide "little or no therapeutic improvement" what would the appropriate new price test be?

As indicated above, Pfizer wishes to see the regulatory burden reduced, not complicated further, by the introduction of new categories and price tests.

Q3 - For price review purposes, "comparable medicines" are medicines that are clinically equivalent. Do you have any suggestions as to principles or criteria that should be used in determining how to identify "comparable medicines" for the purpose of inclusion in the above price tests?

As mentioned above, the PMPRB should be looking to accomplish its mandate of preventing excessive prices of patented medications with a less burdensome regulatory regime. If the proposals outlined above are accepted, then adding further regulation related to the selection of comparable medications will not be necessary. If they are not, then Pfizer concurs with the Rx&D position that the PMPRB should adopt an expansive definition of comparators, which will permit maximum flexibility in terms of potential comparisons.

Q4 - Under the current Guidelines, Board Staff compares the Canadian average transaction price of the new medicine to the prices of the same medicine sold in the seven countries listed in the Regulations. However, Section 85(1) of the Patent Act states that the Board should take into consideration "the prices of other comparable medicines in other countries". Should the Guidelines address this factor?

Consistent with its previously stated views that the PMPRB ought to be seeking to minimize the introduction of new regulatory mechanisms, Pfizer does not favour the addition of such a consideration unless it is used exclusively as a last resort when all other available mechanisms prove inadequate for identifying an MNE price.

<u>Issue 3 – Class of Customers</u>

Q1- Given the price variations by provinces/ territories and classes of customer illustrated in the previous figures, is it appropriate for the Board to only consider an ATP calculated based on the total revenues from the sales for all provinces/territories and all classes of customer? Why? Why not?

As the data from the discussion guide indicate, between 80 and 90 per cent of all products sold in Canada under the jurisdiction of the PMPRB are priced within 10 per cent of the MNE price regardless of the province or territory in which they are sold and regardless of the class of customer. These data demonstrate clearly that there is no justification to consider breaking down the calculation of average transaction price, (ATP) along jurisdictional or customer class lines. To do so would place an additional burden on the Board's resources and on manufacturers with questionable and/or minimal public benefit. Again, moving in this direction would be inconsistent with considering ways to streamline the Board's regulatory oversight activities.

Already, the pricing regulatory framework represents a powerful disincentive for manufacturers to consider offering preferred customers favourable purchase terms due to the impact of such an arrangement on the overall ATP calculation. If the Board would be prepared to consider reducing its oversight and modify its guidelines accordingly, it would provide more opportunity for customers to use their market power to seek a better deal from manufacturers.

Q2 - If the current ATP calculation is not appropriate, should the Board review the prices to the different classes of customers and/or the different provinces and territories for all DINs? Or should this level of review be done on a case-by-case basis, where there is a significant variation in the prices charged?

As stated above, the PMPRB should retain its national approach to calculating ATP and to resist any calls to review individual DINs on the basis of smaller geographical and/or class-of-customer units.