17300 Trans-Canada Highway
Kirkland, Quebec H9J 2M5
Tel. 514-426-7033
Fax 514-426-6831

Pfizer Canada Inc.

Ghislain Boudreau
Vice-President
Public Affairs and Stakeholder Relations

April 27, 2009

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

Dear Ms. Dupont,

Re: Draft Excessive Price Guidelines – Notice and Comment, March 2009

Thank you for the opportunity to provide input on the latest version of the Draft Excessive Price Guidelines.

Pfizer Canada supports the submissions of our industry associations, Rx&D and BIOTECanada.

As you know, Pfizer Canada has significant experience liaising with Board staff on price regulatory issues over the last twenty years, and was an active participant in the working groups that were supposed to inform the guideline revision process. For this reason, I trust that Pfizer Canada's recommendations will be carefully considered and incorporated into the final version of the Guidelines.

In this context, I want to express our disappointment that several of our specific recommendations from our October 6, 2008 submission have not been incorporated into the new version of the proposed guidelines. The purpose of our submission today is to provide details on several outstanding issues, along with suggestions on how the Board should address them.

In particular, this submission addresses Pfizer Canada's positions on five key issues: (1) Canada's experience with price regulation; (2) divergence between the consensus of the working groups and the revised guidelines; (3) application of the Maximum Average Potential Price; (4) timelines for revised guidelines implementation; and (5) confidentiality of certain information provided to the Board.

1. Canada's experience with pharmaceutical price regulation

Pfizer Canada recognizes that the Board was created as part of a public policy trade-off which led to the implementation of intellectual property protections for pharmaceuticals. The Board was established in part to safeguard Canadians from "excessive prices" to counterbalance the market exclusivity granted to patentees.

The Board has recognized on several occasions that the vast majority of patented drug prices in the last twenty years have not been excessive. In fact, the introductory prices of new patented medicines have been well below the maximum non-excessive price (MNE) established by the Board, and the average price increases have been less than those allowed under the consumer price index (CPI) formula. In other words, there is no demonstrated rationale for increased scrutiny on prices of patented medicines.

2. *Divergence between the consensus of the working groups and the revised guidelines*

The PMPRB established five working groups to inform Board staff on the revisions to the excessive price guidelines. Pfizer Canada participated in three of the working groups, and appreciated the opportunity to sort through a series of technical issues with respect to the proposed revisions.

Representatives on the working groups included a broad spectrum of stakeholders, including academics, industry, the payer community, Health Canada and the Canadian Agency for Drugs and Technology in Health (CADTH). Discussions led to a consensus on how to address the issues and concerns Pfizer Canada and others identified. Pfizer Canada's concern is that the revised guidelines appear to have selectively chosen some recommendations of the working groups, while ignoring many of the most significant solutions that the groups proposed. Our experience with and the outcomes of three of the groups underscore several outstanding concerns with the revised guidelines:

a. Working Group on Therapeutic Improvement: The working group agreed that improved patient compliance is of value when considering a drug's level of therapeutic improvement and that proof of improved patient compliance may change a drug's level of therapeutic improvement (4.4 of the group's report). The Board disagreed with the working group (providing no explanation), and now proposes to move forward with the position that secondary factors (e.g., compliance) do not carry sufficient weight to move the level of therapeutic improvement from moderate to substantial improvement.

b. Working Group on the International Therapeutic Class Comparison (ITCC): The working group did not support the inclusion of generic comparators if the price test for the ITCC would be below the "top" of the ITCC (4.2.6 of the group's report). The reason for the working group's conclusion was that the availability, use and price of generic drugs vary widely in the comparator countries. Inclusion of multiple generics would therefore unduly skew any median test results and undervalue patentees' contribution to research and development. The Board (again, with no explanation) is moving forward with the revised guidelines that propose to include generics in the ITCC.

c. Working Group on Price Tests: A key issue for this working group was the de-linking of the average transaction price (ATP) from the maximum non-excessive price when a benefit is provided (e.g., under a compassionate use program). The working group developed two methodologies (DIP & GAP) for de-linking the ATP and the MNE that would go some way to maintaining the existing incentives for patentees to offer benefits, without compromising a patentee's right to appropriate, CPI-adjusted price increases. Unfortunately, the Board selectively chose to move forward with one methodology exclusively (DIP). There are many outstanding technical concerns on how the methodology would be applied in practice and across markets.

3. *Application of the Maximum Average Potential Price (MAPP)*

Pfizer Canada supports the Board's efforts to clarify terminology used by the Board, in particular, the Maximum Average Potential Price (MAPP) and the Non-Excessive Average Price (NEAP). The MAPP as it is currently proposed has no substantive or practical value for the Board or for patentees in the context of determining introductory prices or whether or not prices are "excessive."

For this reason, Pfizer Canada recommends that the MAPP should serve as the basis for the Therapeutic Class Comparison (TCC) Test. An example may help illustrate how this would work. "Pharmaco" launches drug X, a Category 3 product. The Board would under normal circumstances apply the TCC test but the Board finds that there is only one comparator: drug Y, manufactured by "Biopharm." Biopharm launched Y at $10 per day, but Y is now effectively priced (i.e., the NEAP) at $6 because of a benefit (e.g., compassionate use program). Pharmaco wants to launch at $10, but under the proposed guidelines, would not be permitted, because the closest comparator NEAP is $6.

In other words, under the proposed system, the Board would effectively force companies that want to launch new products to offer benefits equivalent to those that competitor companies are providing. This proposed system would go far beyond the Board's mandate to regulate "excessive" prices, would act as a disincentive to launch new products, and would further inhibit market actors (payers and consumers) from determining the value of new products.

As a solution, Board should adopt the MAPP as the basis for the TCC test, which would allow companies to appropriate price products at launch and, when appropriate, offer benefits.

4. *Timelines for revised guidelines implementation*

Pfizer Canada wants to emphasize the concerns of our industry association that the proposed timelines for when the new guidelines would come into effect (July 1, 2009) are unworkable and administratively unfair to patentees. They will not work because the average transaction price

(or the Non-Excessive Average Price) cannot be determined mid-way through a calendar year. Any implementation of revised guidelines for which the NEAP will be applied should begin on January 1 of a given year. Second, any formal revision to the guidelines will impact how patentees need to interact with the Board and the Canadian market in general. Changing the way we do business will require several months, and not the few weeks that the Board is proposing.

5. Confidentiality of certain information provided to the Board

Pfizer Canada is concerned about the Board's proposal to publish all pricing information reported on Form 2, Block 5. Prices filed are actual ex-factory international prices that cannot consistently be derived from the publicly available sources using the Board's current methodology. This is often commercially sensitive and confidential pricing information. The Board has provided no rationale for publishing this information without a patentee's consent. Pfizer has always been committed to protecting its commercial interests and trusts that the Board will not make any publication of information that would contravene the governing principle of confidentiality.

In closing, our four key recommendations are summarized below:

1. Review and adopt the consensus positions of the working groups;
2. Use the Maximum Average Potential Price as the basis for the Therapeutic Class Comparison test;
3. Push back the timelines for revised guidelines implementation until January 1, 2010; and
4. Ensure that the confidentiality of certain information provided to the Board remains a guiding principle in the final version of the guidelines.

Pfizer Canada is encouraged by the constructive working relationship that has been established over the course of consultations on the proposed guidelines. Adopting the above-noted recommendations will go a long way towards improving the Excessive Price Guidelines and the Board's ability to fulfill its mandate.

If you have any questions, please do not hesitate to contact me.

Yours very truly,

cc. The Hon. Leona Aglukkaq, Minister of Health
The Hon. Tony Clement, Minister of Industry