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Pfizer Canada Inc.

Ms. Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Re: Proposed Amendments to the *Patented Medicines Regulations* (Notice and Comment)

Dear Ms. Dupont,

This letter and attached documents constitute Pfizer Canada's response to the Notice and Comment document, published in early February 2005, regarding Proposed Amendments to the *Patented Medicines Regulations* (*Regulations*). We thank the PMPRB for the opportunity to comment in advance of the formal regulatory review process.

Pfizer fully supports Rx&D's response to the Notice and Comment and we have attached a copy of that response for your reference. We would like to draw your attention to the salient points of the Rx&D submission and elaborate further on a number of points.

Overall, Pfizer would submit that this regulatory initiative is an over reaction to recent events. While it is true that there have been some pricing adjustments introduced by some pharmaceutical manufacturers, there is no reason to believe that these minor increases jeopardize the Canadian pharmaceutical pricing regime. These are the first price increases in more than a decade and the Board has acknowledged they appear to be within the established regulatory framework. The market has been effective at restraining price increases and there is no reason to believe this dynamic will not continue to work. Pfizer has specific concerns with several of the proposals outlined in the Board's document as described in more detail below.

First, Pfizer is concerned that these regulations will delay patients' access to innovative medicines. The first proposed regulation introduces a new 60-day delay before patients can begin benefiting from a new medicine. The Bain report[1] showed how Canadians already experience significant delays in access to medicines compared with the U.S. and European countries (see Figure 1). This draft regulation would add a further delay possibly jeopardizing the health of Canadians.

Second, Pfizer believes the proposed regulations will harm innovation. This will impact the development of new medicines for patients and reduce the potential for future investment in Canada. The negative impact on innovation will result because the

[1] Bain and Co., The Economic and Health Impact on Canada of Pharmaceutical Regulations and Pricing Policy, Sept. 2004.

proposed regulations are unlawful, and contradictory to the expressed will of Parliament. The Patented Medicines Prices Review Board (PMPRB) was established to prevent excessive pricing and foster the development of a research based pharmaceutical industry. These proposed regulation changes, combined with the continued deterioration in Canadian access, time to regulatory approval and intellectual property conditions, will result in a worsening of the Canadian pharmaceutical investment climate. The Canadian investment climate makes it increasingly difficult for innovative enterprises in the Life Sciences sector to compete for the kind of investment that will make Canada a 21st century economy. Adding further regulatory oversight to an already highly-regulated commercial environment for negligible improvements or even deterioration in timeliness is counter-productive to the country's economic development interests.

Third, while Pfizer applauds the PMPRB's desire to improve the timeliness of its reviews, it appears that the proposed regulations will add inefficiencies to the already heavily regulated process of price review for patented medicines. Many of the proposed changes would increase the detail and frequency of price data reporting, thereby increasing the workload of the PMPRB and further delaying the timeliness of response.

Fourth, these proposed regulations will impose an unreasonable regulatory burden which is contrary to the intent of the Smart Regulation initiative recently announced by Minister Alcock. Requiring the industry to file price data before launch and price increases as well as detailed calculations for Average Transaction Prices creates duplication and an enormous amount of work for little gain in regulatory effectiveness. The PMPRB already has ample authority and mechanisms to carry out its mandate. This is not the kind of value-added regulation envisioned under the Smart Regulation initiative.

Finally, we have concerns with the review and disclosure of draft product monographs. It is not clear how the efficiency of the PMPRB is improved by the review of a draft Product Monograph (PM), which, by definition, has not been approved by Health Canada. Further, a draft PM represents 'work in progress' and should be expected to differ from the final approved PM. The draft PM may contain information that may ultimately be absent in a final PM. Therefore, if the draft PM was reviewed by the PMPRB and then later revised prior to the issuance of the Notice of Compliance, it would no longer be applicable to their initial review. This would result in a re-assessment by PMPRB based upon the final approved PM adding further inefficiency to the process.

In addition, the *Food and Drugs Act* and its accompanying regulations make no explicit reference to the existence of a PM. The development, and use, of PMs have been the subject of administrative policy. As a result, we believe that the PM should remain part of the administrative documentation of the drug regulatory approval process and should not be subject to such statutory provisions.

If the PMPRB were able to require draft product monographs, there must be new safeguards put in place to ensure the protection of confidential information. This would be consistent with the practice of the Access to Information and Privacy Centre of Health Canada, that PMs are not disseminated prior to launch. Pfizer Canada strongly supports the dissemination of approved PMs, but cannot agree to widespread public availability of unapproved versions. Please note that all of Pfizer's approved PMs are accessible through the Pfizer website.

In closing, while Pfizer is supportive of the amendments regarding veterinary filing requirements and electronic signatures, it is deeply concerned over the appropriateness, justification and intentions of the remaining amendments. Therefore, we would request that no further action be taken by the Board in this regard.

Please feel free to contact the undersigned to clarify any of the comments above and we look forward to meeting with you and explaining in our concerns in more depth.

Sincerely,

Jean-Michel Halfon
President, Pfizer Canada

Encl.