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VIA E-MAIL AND COURIER

April 27, 2009

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,

In reference to the updated *Draft Revised Excessive Price Guidelines* issued by the PMPRB on March 26, 2009, Shire Canada Inc. ('Shire Canada') wishes to offer the following comments regarding the document and the associated consultation process for your consideration.

As in the past, I wish to make it clear that Shire's feedback should be viewed as a supplement to the Canada's Research-based Pharmaceutical Companies', (Rx&D's) submission. Shire Canada is in full agreement with the Rx&D submission and endorses its positions without exception. Therefore, when considering the input that follows, please ensure that you consider the Rx&D perspective as an integral part of Shire's views as well. Our comments are intended only to build on and clarify the Rx&D's point-of-view from the perspective of a regulated patentee.

Before addressing the specific proposals outlined in the PMPRB discussion paper, I wish to note Shire Canada's concern again about this whole reform exercise. As stated in my previous correspondence related to an earlier draft of the proposed guidelines, (dated October 6, 2008), Shire questions the necessity for the changes under consideration.

As I pointed out then, given the patented pharmaceutical industry's exemplary record of compliance and a continuing lack of excess price-related pressure on the marketplace, there does not appear to be any public policy justification for making substantive changes to the way the PMPRB manages its regulatory functions. While some minor adjustments may be called for (in light of the board's determinations regarding Adderall XR® as an example), there does not appear to be any valid justification for the far-reaching and resource intensive reform exercise to which the board staff and affected stakeholders have been subjected since 2006.

Moreover, even if a compelling argument could be made for a significant upgrade to the board's existing policies and procedures, one would hope that the result would be an improvement over the current regime, or at very least, a lessening of the regulatory

burden. Unfortunately, in addition to being unjustified, the current exercise certainly does not meet those simple tests. In fact, as the process unfolds, it gets ever more

complex, confusing and unpredictable, with each new objection from affected stakeholders resulting in the board announcing new measures and proposals, each designed to "clarify" the board's position further and address concerns through layering on more obligations and requirements. From Shire's perspective, that suggests the need for the board to consider again what it is trying to accomplish with these reforms and for what public policy purpose. If, as I believe, the proposed solutions are worse than the problem they are designed to fix, then they should be abandoned.

Another general observation that I would like to make is that that the board appears to have a different view about what constitutes consultation than we hold. While Shire Canada appreciates and acknowledges that the board has demonstrated an increasing willingness to hear the industry's views, the resulting proposals indicate that it has not really listened to the feedback received.

In analyzing the board's response to the recommendations made by the Rx&D during the last phase of this consultation process, it appears as though the board has rejected the majority of the suggestions made. Of the 17 substantive recommendations made by the Rx&D in October 2008, the updated guidelines reflect only three (none of which relate to the most important concerns). Of the remainder, nine, (including the most vital elements) appear to have been rejected outright, three remain unacknowledged, one was addressed only in part and an attempt was made to deal with another, but unsuccessfully. Moreover, the board has proposed a series of additional operational changes and policies which have not been part of the discussions up to this point. Taken together, these actions lead us to wonder whether the time and effort invested to address the board's proposals and recommend alternatives have been for naught.

However, in a spirit of dialogue and in the hopes that the industry's views will be considered fully, we would like to emphasize a number of points which Shire does not believe to have been addressed satisfactorily in the updated draft guidelines.

First, we continue to be concerned by the board's attempt to extend its mandate to include a consumer protection element which is not addressed in the legislation. We encourage the board strongly to respect the balance inherent in its original mandate and to avoid characterizations which could be used to justify further expansion of its regulatory reach and scope.

Second, while we support the addition of a new "moderate improvement" category to differentiate new entrants from existing medications, Shire would prefer to see the board take steps to minimize the need for evaluations of therapeutic differences and complicated price tests between different medicines.

Third, every effort must be made to avoid creating dis-incentives for manufacturers to offer commercial benefits to customers in appropriate circumstances. In Shire's view, board efforts to regulate prices taking account of such financial considerations goes well beyond the monitoring function envisioned for the board when it was created and undermines the efficient functioning of the marketplace. The confusion which has accompanied the board's efforts to regulate in this manner so far, and the complexity of the proposed solutions, are a reflection of the folly of trying to control an intricate marketplace artificially and a pre-cursor to further chaos as the inevitable attempts to

address numerous exceptions going forward add layers onto the process. Worse yet, if it is pursued, it will likely result in higher, not lower, prices since manufacturers faced with

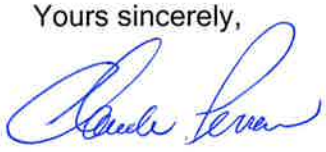
the prospect of being forced to reduce prices across-the-board due to financial considerations offered to individual customers, could choose simply to avoid offering any deals at all.

Fourth, Shire remains steadfastly opposed to the notion of extending PMPRB's price review function to the provincial level and, more importantly, to conducting inter-market segment comparisons. Keeping in mind that the PMPRB's mandate is intended to ensure that the prices of patented pharmaceuticals are not excessive, it should be sufficient for a patentee to demonstrate that no price charged to any customer in Canada exceeds what is considered to be "excessive". Different prices charged to different customers that are below that amount should not be the board's concern.

Once again, Shire Canada appreciates the opportunity to contribute its views to this important debate. We urge the board to give full consideration to these comments, in conjunction with the positions expressed by the Rx&D before proceeding with any changes.

However, given the scope and potential implications associated with the board's current proposals, we would prefer to engage in a more interactive dialogue with the board and other interested stakeholders to address the underlying issues which are driving these reforms before they proceed. It would be ideal if the board would consider its needs again, articulate what it hopes to achieve and then, invite relevant stakeholders to contribute ideas and proposals to address those identified needs. Once multi-stakeholder consensus is achieved on what needs to be changed, then the discussion should shift to how those objectives could be practically achieved. That would represent true reform.

Yours sincerely,



Claude Perron
Vice President and General Manager

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