

PURDUE

PATENTED MEDICINE
PRICES REVIEW BOARD

Purdue Pharma

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April 11, 2005

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Ms. Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West
Ottawa, Ontario
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CONSEIL D'EXAMEN
DU PRIX DES
MÉDICAMENTS PRÉVETÉS

050399

3225-3-13

Dear Ms. Dupont:

Subject: **Proposed Amendments to the Patented Medicines Regulations**

This letter is in response to the proposed amendments that appeared in the PMPRB's "Notice and Comment", dated January 2005.

The reference to the *Timelines Project* is noted, and as an R&D-based pharmaceutical company, Purdue Pharma has previously commented on what appear to be unduly lengthy periods of time for the Board to complete its review of pricing submissions. However, we also believe that the Board – in the Notice and Comment – is overstating the extent to which those lengthy reviews are a result of the timing of the data filed by patentees. Moreover, we believe that some of the proposed changes are highly likely to exacerbate the timeliness of price reviews – by virtue of requiring the submission of superfluous information. Our comments on the specific proposals are:

Notification of a Proposed Price

The current Regulations result in the Board receiving the price at which a medication is being sold – no less than 60 days after the medicine is first sold. It is this price (actual selling price) on which the PMPRB exerts jurisdiction. In many instances, the price over which a medicine is going to be sold is not "finalized" substantially prior to the medicine actually being sold – and certainly not 60 days prior. The proposed change, if implemented, is likely to result in patentees filing "tentative" prices, which turn out to be different from the actual prices. There is simply no way in which such an outcome, even if only for a small percentage of new medicines, is going to increase the Board's efficiency.

As such, we believe that the current requirement to notify the Board of the actual selling price within 60 days is preferable. An alternative that also seems acceptable would be for the company to notify the Board of the actual selling price(s) on the date of first sale.



Notification of a Proposed Price Increase

The PMPRB has jurisdiction over actual selling price, not proposed price increases. Moreover, the Board's Guidelines with respect to price increases (limited to changes in the CPI) are well known to patentees. Finally, because of varying dates of provincial drug formularies' revisions, price increases sometimes take effect on different dates across the country. As such, a fixed percentage price increase may well turn out to be a lesser increase when analyzed within the context of a 6-month reporting period. This proposed amendment is also one which is going to decrease – as opposed to increase – efficiency, and should not be pursued.

Details on the Calculation of Net Price and Net Revenues

Purdue is willing to help the Board understand how the calculation of net price was performed, but we do not believe that the proposed mechanism of revising the reporting forms is an efficient mechanism by which to achieve this objective. Fixed forms, especially those output from IT systems, are much less able to convey the information as to how the patentees came to the calculation than a brief narrative describing the data used in the calculation, and the calculation process itself.

Product Monograph

Purdue will gladly provide a Product Monograph to the Board at the time of notification of the price at which a new drug is being sold.

In addition to the above comments, Purdue supports the proposed changes pertaining to *Recognition of Electronic Signatures, Filing Requirements for Veterinary Patentees and Editorial Corrections.*

We hope that you find these comments of value, and look forward to hearing of the direction the Board ultimately chooses to pursue.

Regards,

A handwritten signature in black ink, appearing to read "Lance W. Payne".

Lance W. Payne, B.Sc.Pharm., Pharm.D.
Director
Federal & Provincial Regulatory Affairs

C: Andrew Darke
John Stewart

LWP:vt