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Shire

October 6, 2008

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 PMPRB discussion paper released on August 20, 2008 entitled *Draft Revised Excessive Price Guidelines,* Shire Canada Inc. ('Shire Canada') wishes to offer the following comments regarding the document and the associated consultation process for your consideration.

To start, please let me clarify that this feedback is offered as a supplement to the submission that you have received already in this regard from Canada's Research-based Pharmaceutical Companies, or Rx&D. As a full member of the association, Shire Canada has been fortunate to have participated in the development of the association's perspectives on the issues outlined in the discussion paper.

Overall, we agree unreservedly with the concerns expressed by the association and fully support the views and recommendations found in the Rx&D submission. The comments which follow are intended only to augment those views from the perspective of an organization which faces the prospect of having to operate within the terms of the proposed Guidelines. Therefore, please ensure that, when considering Shire Canada's input, you treat the Rx&D positions as an integral component of our views and give them due consideration in that light.

As a preliminary observation, I will just say that after reading through the discussion paper and accompanying draft Guidelines, I am daunted by what is in store for patentees if these proposals go forward as presented.

Shire urges the Board to appreciate that the primary goal of the 1987 and 1993 amendment to the Patent Act was to encourage innovation and economic development in the pharmaceutical sector by restoring intellectual property protection rights to manufacturers, which had been denied, to them since the late 1960's. The PMPRB was established solely to ensure that a reasonable balance could be maintained between the creation of important incentives for

pharmaceutical industry investments and protecting the citizenry against any extreme attempts to exploit the new regime through unreasonable pricing practices. It was intended to play a largely passive regulatory role, not to intervene actively in the marketplace.

With that in mind, I consider the record of Canadian pharmaceutical patentees in terms of responsible pricing practices during the twenty years the Board has been operating. Let me stress that throughout that timeframe, Canadian product prices, on average, have ended up within a few percentage points, (plus or minus) of the international median (or mid-range) of prices for the same medications available elsewhere. During the same time period, average annual price increases have never amounted to more than five per cent in a given year, and since 1992, have averaged **less than one per cent**. Moreover, the industry's record of compliance with introductory price restrictions consistently has been exceptionally high. Despite that, I see an agency which continually has sought to extend its regulatory reach into the Canadian pharmaceutical marketplace, which demands increasingly complex, time-consuming and expensive reporting by patentees and which more and more frequently rejects negotiated agreements to settle dis-agreements in favour of formal Board hearings.

Given the above, Shire Canada fails to appreciate the need for further intervention by the Board in the marketplace, as contemplated by these proposals. In reality, it is probably appropriate, in light of the industry's stellar record of compliance and the absence of any trend which would suggest otherwise, to ask why the Board is not doing its best to reduce its oversight and experiment more with allowing market forces do the heavy lifting in terms of moderating pricing practices.

Regarding the specific proposals proposed by the Board, there are three on which Shire would like to make additional comments to those offered in the Rx&D submission.

<u>Evaluations of Therapeutic Improvement</u>

Shire Canada questions the public policy rationale supporting the Board's practice of evaluating medicines on the basis of therapeutic improvement. By our way of thinking, the only reasonable consideration which should be utilized in assessing "excessive" pricing is whether a new medicine is priced outside the norm when compared with other medications used for treating broadly similar illnesses. If a new medicine is priced higher than a normal range for similar treatments, then it might be reasonable, in a regulated environment, to question that price. To go beyond that simple approach leads to the Board having to make judgement calls regarding what makes one alternative "better" than the next and how much each variation is worth.

Shire Canada recommends that instead of attempting to further refine an already faulty, lengthy, onerous and complex process for determining relative therapeutic improvement, the Board should consider simplifying its current process by largely eliminating the necessity for the Human Drug Advisory Panel and the accompanying litany of multi-tiered pricing tests in favour of a straight therapeutic class comparison, supported by international price comparisons (in cases when a straight TCC comparison is not appropriate).

Having said that, it appears clear that approach is not likely to find enough favour to be implemented in the short term. Recognizing that, Shire wishes to acknowledge the proposed addition of a fourth level of therapeutic improvement which, one hopes, will allow for finer distinctions when comparing medicines for price review purposes than is currently possible. We endorse the addition of the new category as a reasonable compromise intended to address the industry's long-standing concerns about a lack of recognition for legitimate gains in incremental innovation.

Reporting of Financial Benefits

Shire Canada believes that the requirement for patentees to report the value of financial considerations associated with the provision of medicines under the terms of compassionate use programs is counter-productive to everyone's interests. Requiring patentees to do so will mean simply that they will not be in a position to offer such benefits at the risk of being penalized in the marketplace as a result.

Ironically, that is a situation which, if it does not simply deny patient access to needed medications, will force customers to pay higher prices for something that otherwise could be provided free-of-charge or at a drastically reduced price. Therefore, Shire Canada recommends that all efforts be made to find a way to exclude any calculation related to benefits provided as part of a compassionate use programs from the determination of the average transaction price (ATP).

In recognition of the fact that the Board has interpreted the Federal Court decision related to Dovobet as effectively eliminating any discretion regarding whether or not to require the reporting of the commercial value of medicines supplied for compassionate use, Shire proposes that the Board consider simply collecting the data, but refrain from applying that value to the calculation of the ATP.

"Any Market" Reviews

In determining how to segment the marketplace for the purposes of facilitating a price review in "any market", Shire Canada believes that the Board should limit itself to considering only the four original market segments defined by the Board (i.e., wholesalers, pharmacists, hospitals and others). It should refrain from extending its jurisdiction into geographic market segments.

To do so, would have a significantly deleterious effect on the ability of a patentee to use financial considerations to differentiate themselves in the market place or negotiate any type of preferred financial arrangement whatsoever. This would ensure that prices would remain high and public payers in Canada, who continually insist that they should be treated more like traditional customers, will be unable to encourage any deal-making with a financial consideration. How would that serve the public interest?

The only way such a process could be considered would be if the Board agrees to the full de-linking of ATP from maximum non-excessive (MNE) price as recommended by the Working Group on Price Tests. If the MNE remains at the level of the introductory price, then the issue of "any market" price reviews would be less of a concern. However, based on the Board's draft proposals, the prospect of being forced to reduce medication prices nationally as a result of a financial benefit offered to a smaller sub-set of customers will ensure that no financial considerations ever would be contemplated by patentees.

In addition to addressing the three issues of special concern above, Shire also would like to respond to the Board's request for specific feedback on the CPI cap and the calculation of excessive revenues following an "any market" review.

CPI Cap

Shire Canada believes that the protection offered by the CPI cap methodology is outdated in the current marketplace environment and should be eliminated. Given the challenges faced by patentees in obtaining any price increases whatsoever, regardless of inflationary considerations, due to provincial reimbursement policies and other prevailing market factors, there is really no reason for the mechanism to be retained.

Calculation of Excess Revenues Following an "Any Market" Review

The discussion paper seeks comments on the appropriate mechanism to be used when calculating excess revenue after an "any market" review finds a given price to be excessive. From Shire Canada's perspective, the Board must not isolate the experience in the market which is deemed to be "excessive" from the calculation of excess revenues. This would ensure that the excess revenues would be higher than if the whole marketplace would be considered and would be unfair to the patentee.

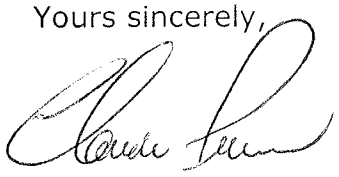
Concluding Remarks

As indicated above, these observations address only the most urgent issues arising out of the draft discussion document issued in August. This is because, as a relatively smaller company, we simply do not have the luxury of investing in a detailed, line-by-line analysis of the extensive reforms proposed by the Board. Fortunately, we are able to rely on the excellent analysis provided by Rx&D and we urge you to take full account of what the association has raised. However, I would also ask the Board to re-consider how it undertakes such consultations in the future.

The sheer scope and breadth of the changes proposed in the draft Guidelines are extensive and wide-ranging. In order to review and assess all of the proposals properly, (individually and in combination with each other), it would require a significant investment of additional time and resources to which companies like Shire simply do not have ready access. This makes the job of responding quite time-consuming and burdensome for companies in an increasingly dynamic business environment. Therefore, Shire would request that the Board consider how to re-orient the current consultations such that the various questions can be addressed in a more manageable and balanced fashion which would allow for appropriate dialogue and reflection. Failure to do so, may lead to unintended consequences and continued dissatisfaction on the part of stakeholders.

Thank you for the opportunity to comment. We look forward to further revisions in the content of the Guidelines and in the way in which the proposed reforms are undertaken.

Yours sincerely,



Claude Perron
Vice-President and General Manager

c.c. The Hon. Tony Clement, Minister of Health
The Hon. Jim Prentice, Minister of Industry