Canada's Research-Based Pharmaceutical Companies (R&D) Les compagnies de recherche pharmaceutique du Canada

President's Office / Bureau du Président

October 22nd 2007

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

Re: Regulations Amending the Patented Medicines Regulations, 1994

Dear Ms. Dupont:

On behalf of *Canada's Research-Based Pharmaceutical Companies* (Rx&D), I am writing to you with respect to the proposed amendments (Amendments) to the *Patented Medicines Regulations, 1994* announced by the Patented Medicine Prices Review Board (PMPRB) in the Canada Gazette (Part I) on October 6th, 2007.[1]

The Amendments in Context

These latest proposed regulations and accompanying Regulatory Impact Analysis Statement (RIAS) are a re-publishing of regulations that were first published on December 31st 2005. When these were originally published, they were described as "minor changes to some processes followed by patentees in submitting price and revenue data". However, as noted in its submissions on the Amendments and during discussions with the PMPRB, Rx&D respectfully disagreed with this description.[2] Several of the proposed Amendments represented significant alterations to the PMPRB's Regulations and would have the effect, if implemented, of creating an additional regulatory burden for patentees.

While Rx&D notes that some significant changes have been made from the original package we are very concerned that patentees' comments regarding some of the Amendments have not been given adequate consideration, and that proposals made by Rx&D to streamline the process and improve the efficiency of the PMPRB have apparently been ignored.

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[1] Regulations Amending the Patented Medicines Regulations, 1994, Canada Gazette Part I, October 6th, 2007.
[2] Please see Rx&D Response to the Proposed Amendments to the Patented Medicines Regulations, January 30th 2006 and April 7th, 2006.

Major Jurisdictional and Policy Issues

1. Patentee Provision of Draft Product Monographs

> ... patentees will still be required to submit, if a NOC has not been issued in respect of the medicine, information similar to that contained in a product monograph. The proposed requirement that a product monograph be provided in cases where a NOC has been issued has not changed.

Rx&D's position on this issue remains unchanged from our previous submissions.

Rx&D has confidentiality concerns with respect to the filing of draft monographs (or information similar to that contained in draft monographs). These documents contain highly sensitive information that the patentees do not wish to see disseminated any further than absolutely necessary, even if received in confidence. It is also our understanding that the Therapeutics Products Directorate of Health Canada has expressed concerns regarding the distribution of draft product monographs that are still under review.

Additionally, draft monographs (or information similar to that contained in draft monographs) submitted to the PMPRB may be revised, forcing PMPRB to repeat work based on the final monograph, and thereby compromising its efficiency.

While Rx&D understands that some patentees may already provide product monographs to the Board voluntarily, we are unaware of any situation where a patentees has refused to provide a product monograph voluntarily and where PMPRB has been required to issue an order to secure such a document under these circumstances, the principles of Smart Regulation should apply, in that regulatory requirements should be imposed only where there is a demonstrated need.

2. Reduction in Filing Timelines for Information Respecting the Identity of the Medicine

> The PMPRB has notified Rx&D it is now proposed that the timeline for provision of this information be changed to the earlier of seven days after the date of issuance of the first NOC in respect of the medicine, or seven days after the date on which the medicine is first offered for sale in Canada.

Rx&D is opposed to this amendment on the basis that it seems inconsistent with reporting requirements of other regulatory agencies. For example, under *Food and Drug Regulations*, manufacturers have 15 days from receipt of information to report a serious adverse drug reaction to Health Canada. It seems disproportionate that Health Canada's timeframes with respect to the reporting of serious adverse reactions are more lenient than the PMPRB's proposed filing deadlines related to pricing issues. Rx&D suggests that reasonable, practical and proportionate filing

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requirements are in the best interest of both patentees and the Board. In the absence of a convincing rationale, the status quo with respect to the filing of Form-1s should be maintained.

3. Reduction in Filing Timelines for Price and Sales Information for the First Sales of the Medicine

> The PMPRB will still request data for the first day of sales only, but it is now proposed that the deadline for filing remain at the current 30 days after the day on which the medicine is first sold in Canada.

Rx&D remains unclear with respect to the public policy rationale for this amendment, as there seems no tangible benefit derived from changing this regulation from its current position.

4. Average Price Calculation

> ... patentees would be required to report the types of benefits deducted in the average price calculation, but not the amounts of each benefit. To further lessen the burden of implementation on patentees, the regulatory amendment respecting identification of specific types of benefits has been changed so that it would come into force on July 1, 2008, and not immediately following publication in the *Canada Gazette*, Part II.

In Rx&D's view, this proposed change represents the most serious issue for patentees with respect to the Amendments. Rx&D remains strongly opposed to this amendment because it will create an onerous reporting burden at significant cost to patentees without creating any material benefits for the PMPRB. The detailed information sought by the PMPRB through these amendments is rarely required for the PMPRB price review process. In the unusual event that it is required, patentees provide it upon request from the PMPRB. In the event that this information is not provided voluntarily, the Board can issue an order under section 81 of the Act that will compel the patentee to provide the required information. It is our understanding that patentees provide the information requested by the Board in a timely manner.

The additional burden imposed on patentees by this proposed amendment seems highly disproportionate to the objective. Isolated requests for additional data can be more efficiently addressed by the Board through telephone calls or emails to the patentees. This new proposed requirement is contrary to the objectives of the Smart Regulation initiative, which aims to make regulation a source of competitive advantage not a burden.

While we accept the PMPRB's comments that it is not their intention to discourage the development of such programs, and acknowledge that the implementation of this change will be delayed to allow for adjustments, there is still no convincing policy rationale for a change that will definitely increase the regulatory burden for patentees, and that may in practice discourage discounts and programs to the detriment of Canadian patients.

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5. Veterinary Drugs, and Over-the-Counter Drugs for Human Use

... would be regulated on a complaints-based approach. Patentees will be required to provide price and sales information to the Board within 30 days after the date on which the Board sends a request in response to a complaint respecting the price of a medicine.

Rx&D supports the amendment respecting non-prescription and veterinary drugs. This positive amendment should be expanded to include patented drugs subject to generic competition.

This proposed amendment would create efficiencies for PMPRB and for patentees by reducing filing requirements for over-the-counter products and lessening the overall price review burden at the PMPRB given that the final prices of these products are determined at the retail level (i.e., not by the patentee) and that consumer choice fosters significant competition that moderates prices.

Rx&D believes that patented prescription drugs subject to generic competition should also be included in subsection 3 definition. Once generics enter the market, the price of the patented version is irrelevant given that there is mandatory substitution in all provinces to the lowest cost alternative. Moreover, the underlying premise of regulating drug prices through the *Act* is to ensure that patentees do not abuse their patent monopoly by charging excessive prices. Once that monopoly is lost and generic competitors appear, the rationale for continued price regulation is highly questionable.

There is no purpose in continuing to regulate the prices of medicines that have been genericized since these prices are already controlled by provincial regulations and policies. Moreover, the PMPRB could realize further efficiencies and patentees would benefit from a reduced reporting burden if it treated these genericized products in the same manner that it intends to treat veterinary and non-prescription drugs. Rx&D would be pleased to work with the PMPRB on this change in order to introduce meaningful efficiencies for both the Board and stakeholders into the price regulation system.

Thank you for your attention with respect to this matter, and please do not hesitate to contact me should you require further information.

Sincerely,

Russell Williams
President

RW/pw