



Bristol-Myers Squibb Canada

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Wayne J. Quigley
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

Dear Ms. Dupont:

I am writing on behalf of Bristol Myers Squibb Canada (BMS Canada) with respect to the proposed amendments to the Patented Medicines Regulations, 1994, announced by the Patented Medicine Prices Review Board (PMPRB) in the Canada Gazette (Part I) on October 6, 2007.

As indicated in the Regulatory Impact Analysis Statement (RIAS), these new regulations are the culmination of consultations which began when the initial regulations were published on December 31st 2005. Before commenting on individual regulations, we would like to address some of the issues raised by a process that took two years to complete.

As you and the Board are well aware, significant decisions are made every day by pharmaceutical companies, decisions on whether, when and how a drug is launched in Canada; decisions, about when and how to bring a drug to market once the decision to launch is made and then decisions on pricing and reimbursement. In this very complex and challenging process there needs to be some sort of regulatory stability.

Instead, pharmaceutical companies have been coping with a challenging period of regulatory flux, with the PMPRB and with other rule-making bodies. As a consequence, internal decision making becomes much more laborious and cautious, which in turn can lead to drugs not being offered to Canadian patients in a timely fashion, or worse, not being available at all.

While we may not always agree with the PMPRB regulations and decisions, we need to be able to discuss those disagreements in a manner that leads to an informed and timely

resolution. In our estimation, the best way to do this is through greater engagement on both sides.

Towards that end, we are pleased PMPRB staff and Board have embarked on the path of more open dialogue. Recent meetings between Rx&D and the Board are a positive step, as are the meetings between Board members and individual company representatives. We hope this becomes the rule that guides future decision and rule-making at the Board, rather than the exception, and we will co-operation to help make this a reality.

With that in mind, we would like to offer our comments on the proposed regulatory changes.

Firstly, we are supportive of the amendment on over-the-counter drugs for human use.

With respect to the proposed regulation on average price calculation we have several concerns. First, it places an additional reporting burden on the patentee, one that is onerous and inconsistent with overarching government initiatives to reduce unnecessary regulation.

Given the PMPRB already has the ability to collect this information when it is required on a case by case basis, we don't believe it is a reasonable solution therefore to compel all patentees to incur the additional costs to produce information, which, may or may not be required by the Board.

In fact, current systems and resources in place do not allow BMS Canada to meet new proposed amendment. This new requirement will necessitate a significant financial investment in programming, new system quality assurance measures, as well as additional employee training.

Thank you for the opportunity to comment on the proposed regulations

Sincerely,

A handwritten signature in black ink, appearing to read 'W. Quigley', written in a cursive style.

Wayne J. Quigley
President