BROGAN INC.
HEALTH CARE DATA RESEARCH . CONSULTING

April 27, 2009

Dr. Brien Benoit
Chair, Patented Medicine Prices Review Board
c/o Ms. Sylvie Dupont
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario, K1P 1C1

Dear Dr. Benoit,

Thank you for the opportunity to provide comments on the proposed Guidelines as published in March 2009. My comments will focus on two issues: comparator pricing and publication of international price comparisons. As you may be aware, I was involved in the drafting of the Patent Act changes at the time the Patented Medicine Prices Review Board was created and have been following PMPRB activity ever since.

By way of executive summary of my attached submission, I offer the following points:

1. Publication of international price comparisons.
   Section 87 privilege protects "any information or document" submitted by a patentee in the context of price review. The Board does not have the authority to disregard this protection, regardless of the circumstances.

2. Comparator Price Selection
   The revised Excessive Price Guidelines provide new wording in relation to the selection of comparator pricing. The new wording indicates that pricing of comparators for introductory price test purposes will consider the non-excessive average price (NEAP). Relying on competitor NEAP information contravenes the protection of Section 87 not to mention the transparency tenants espoused by PMPRB. Furthermore, this policy will result in reducing prices for new entrants moving forward. The mandate of the Board is solely to ensure prices of patented medicines are not "excessive".

Once again, thank you for the opportunity to comment.

Sincerely,

BROGAN INC.

Tom Brogan
President

303 Terry Fox Drive. Suite 300 Ottawa. Ontario. K2K 3J1 t 613.599.0711 f 613.599.4939 www.broganinc.com

PMPRB Notice & Comment: March 2009
Draft Revised Excessive Price Guidelines for Comments by April 27, 2009
Brief Comments
Brogan Inc.

1. Publication of international price comparisons

The Notice & Commment document indicates that:

> "the Board is of the view that since the Form 2, Block 5 information is by definition required to be publicly available, it will no longer be considered privileged information under Section 87(1) of the Act."

On this point, the comments are very straightforward. Section 87 (1) of the Act provides the following clear protection that is not limited to the type, source or level of confidentiality of the information.

> "Subject to subsection (2), any information or document provided to the Board under section 80, 81 or 82 or in any proceeding under section 83 is privileged, and no person who has obtained the information or document pursuant to this Act shall, without the authorization of the person who provided the information or document, knowingly disclose the information or document or allow it to be disclosed unless it has been disclosed at a public hearing under section 83."

Subsection 2 does provide for exceptions; however, these exceptions relate to hearings or reporting to Parliament where the patentee cannot be identified. The privilege extends to ANY INFORMATION OR DOCUMENT. As such, I must strongly disagree with the Board's proposed interpretation.

It is very concerning that a government agency is giving interpretation that is entirely contradictory to a very clear legislative provision. This overt decision by a law enforcement agency to not abide by the law sets a dangerous precedent and is a disconcerting indication of the Board's intentions.

2. Comparator Price Selection

Section 2 of Schedule 3 (Therapeutic Class Comparison Test) addresses the methodology to be applied in determining the appropriate price for comparison purposes. The changes proposed to this section, some of which have reportedly been in place for some time according to Board Staff will have a substantive impact moving forward, particularly, if less flexibility in the provision of benefits is the result of the judicial review scheduled for June. I can only conclude the intent of this change is to lower drug prices in Canada and for the Board to disassociate itself with its mandate to ensure drug prices are not excessive. The means to achieve this unreasonable goal is also unacceptable, in that the confidential information submitted by one patentee under Section 87 privilege is relied upon in the price review of a drug from another patentee and information, by inference – even if not directly, is provided to the second patentee breaching the Section 87 protection.

The comparator price selection methodology detailed in the proposed guidelines require the therapeutic class comparison methodology use a proxy measure of the National Non-excessive Average Price as the maximum price against which new drugs are measured in all markets. This means that benefits provided in relation to one product will have the effect of restricting prices of future products in a class, in all markets in which the future product is sold. This means that the change will result in more new drug prices being lower than those which preceded them and that difference will continue to grow each time a new product is introduced. It is very seriously compounded by the Board's intention to force patentees to report payments to governments.

The price erosion effect arises for the following reasons. After a drug is introduced, it will gradually introduce promotional benefits to win contracts with hospitals or other large buyers or for the benefit of consumers. This lowers the average transaction price. Secondly, governments are beginning to require payments in return for formulary listings. If these payments are included, the average transaction price falls further. The new entrant drug does not have hospital or other contracts initially nor does it have payments to government which would lower its price. These concessions follow after some period of time. These price concessions lower the price of the drug for which a higher price has already been found to be not excessive.

If a new entrant is required to compare its price against the lower average transaction prices it will be required to begin at a lower level and then will be required by market pressures to provide discounts, payments to governments and other price concessions. Instead of having price parity with other drugs in the class, these new products will be forced to progressively lower levels by this new price control scheme. This is despite the fact the pre-benefit prices of the competitor products were likely reviewed by the PMPRB and found to be not excessive.

Another important element to this is the fact that a manufacturer will not know what the average transaction price is of its competitors. As the second largest provider of pharmaceutical data and with nearly 30 years experience in the field, I can say with all certainty there is no public source of ex-factory pharmaceutical prices in Canada or anywhere else in the world for that matter. The PMPRB may have such a figure for patented drugs but it cannot release this. The patentee of a new chemical would only be guessing at the allowable prices for comparator drugs (patented or not). This provision therefore makes the patentee's task of setting prices within the Guidelines impossible. It undermines any notion of voluntary compliance and will lead to a full investigation for every new drug and likely a profusion of costly hearings.

While lower drug prices may be attractive for buyers, this poses a very substantial threat to the introduction of new drugs into Canada and to the health of the pharmaceutical industry in this country. The PMPRB operates under a policy regime established in 1987 which balanced many competing forces in meeting a very clear vision of generating more research, providing fair patent protection and meeting international intellectual property protection requirements. Instead this price comparison provision virtually erases that balance and violates the Board's mandate to review prices to ensure they are not excessive.