Brogan Inc. is pleased to provide its comments on the Discussion Paper for Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines.

Principles:

The PMPRB was established as part of a major over-haul of the Patent Act primarily designed to provide appropriate intellectual property rights for the Canadian pharmaceutical industry. While the PMPRB may be focused on "… protecting the interests of consumers" it cannot do that in isolation. To focus on this one principle at the expense of the other considerations would ignore the balance Parliament was seeking. It was for that reason Parliament mandated the PMPRB to ensure patented medicine prices are "not excessive". It did not mandate the PMPRB to ensure "the lowest possible price", or even low prices.

The other relevant consumer interest is to ensure Canadians have access to the latest pharmaceutical technology. Policies and practices which continually result in adversarial confrontations over an acceptable price determination are detrimental to the long-term interests of consumers and depart from the raison d'être of the PMPRB.

The original Board members recognized the Government's intention to balance the competing interests of consumers and industry by establishing clear guidelines under a principle of voluntary compliance. This approach was very successful, resulting in lower drug prices, relatively low level of stress within industry and very few hearings called. Most pricing disputes were resolved at the staff level.

It would appear, from the proposals concerning the price adjustment methodology, that the Board is re-introducing a more balanced approach. We would suggest the restatement of principles to include a commitment to a voluntary compliance regime, which seems to have been overtaken with a more confrontational approach.

Regulatory Changes

The Discussion Paper pays considerable attention to the need to change the administrative policy with respect to reporting sales data and even goes so far as to change the Regulations. This appears to be prompted by the Federal Court of Canada ruling in the Leo Pharma matter and Ontario's Bill 102 which requires drug companies to compensate the Ministry under certain conditions. We suggest a much closer examination of both of these factors, as follows.

The Federal Court agreed that the Board has the responsibility and power to administer the Act and Regulations. The PMPRB administers the Regulations by virtue of "failure to file" penalties available to it. It can and has made a determination of what data should be filed. For example, the PMPRB has exempted the filing of Veterinary and OTC drugs and allows patentees to file or not file certain transactions as long as they

are consistent in doing so. This is sound policy and clearly acceptable to the Federal Court. The absence of any question or comment from the Court about the current policy must be interpreted as acceptance of the legitimate exercise of the Board's power to administer the Act and Regulations. One can only conclude that the Federal Court decision instructs the Board to *consider* all of the data filed by patentees, but the patentee may determine what data will be filed (within the policy guidelines). The Federal Court decision does not say the Regulations or policy with respect to data filing must change.

The second factor, the PMPRB demand that patentees file the payments made to the Ontario and other governments, has a number of challenges. The provincial governments operate drug programs but are hardly the patentee's customers; therefore any payments to them would not fall under the Regulations. While this requirement by the provinces may be very clever public policy, they are tantamount to a tax on manufactures at one extreme and at very least, a fee for listing. Either way, these payments are certainly outside of the wording and intent of the Regulations. Most importantly, requiring patentees to report on transactions between themselves and a provincial government interferes with the operation of that government. The Board may wish to establish whether it has the legal or constitutional right to ask patentees to report these transactions.

Option 6 takes a strong position against companies providing free drugs to some patients in order to reduce their liability from excessive pricing. The operation of a compassionate program or other method to reduce consumer drug costs by a company seems to be a much more direct and immediate way to resolve a pricing issue than paying the federal government, not to mention being more beneficial to consumers. Option 6 has the appearance of being far more interventionist than intended by Parliament, heavy-handed and unnecessary. Moreover, such exercise of power is inconsistent with the FCC ruling, which was that the Board should include all goods that are reported by patentees, regardless of intent.

While the PMPRB may wish to re-visit the policy on data filing and the regulatory requirements to clarify certain things, there appears to be no good reason to make substantive changes. The current policy has served consumers and industry well. To make major changes without a clear reason for doing so runs the risk of creating a host of unintended consequences that may not be in the best interest of consumers.

CPI Methodology

The current CPI-Adjustment methodology has resulted in a number of price investigations solely due to fluctuations in the Average Transaction Price (ATP) that has little to do with actual price changes. The ATP is not permitted to rise by more than the change in the Consumer Price Index but could fall dramatically as a result of a discount to certain classes of customers (e.g. hospitals), rebates, free goods and other promotional activities. These tend to be of benefit to consumers and companies should not be dissuaded from doing these things. However, the current CPI-Adjustment Guidelines do just that; patentees are reluctant to enter into fixed-period, low price arrangements for fear that they will permanently depress the MNE.

More importantly, pharmaceutical pricing has suddenly become far more competitive than in the past, even to the point of brand companies offering prices competitive with generic pricing. As price competition becomes more pervasive, the price as measured by the PMPRB will fluctuate violently by percentages unheard of in the past. Furthermore, it appears that some generic products have fallen under the PMPRB jurisdiction. Ex-factory price fluctuations in the generic market segment are extreme.

Clearly, the current CPI-Adjustment methodology will not be practical in the new environment. The Board obviously has no interest in discouraging price competition and hence has wisely put forward two options for removing disincentives for price competition and which will significantly reduce the regulatory burden on patentees, not to mention remove the need for extra monitoring rules such as conducting any market reviews and re-setting benchmark prices.

Possible Changes to the CPI-Adjustment Methodology for Determining the MNE Price

The second option proposed for the CPI-Adjustment methodology provides a logical and fair way to define what constitutes an *a priori* finding of an excessive price. We suggest that the establishment of the initial “maximum non-excessive price” would be set entirely on the Patent Act factors and not on the actual price the company was charging at the time of launch. That is, the MNE may be higher than the price at which the company has begun selling the medicine. This removes the incentive to begin selling at prices as high as possible. Admittedly this suggestion goes beyond what is contemplated in the Discussion Paper but is a logical extension of what is proposed.

As far as the CPI-Adjustment methodology is concerned, the suggestion of some limiting cap is a useless addition. In some cases where there have been very deep discounts in a period, there is no reason a patentee should not be permitted to restore its price. In fact, given the oversight by provincial and private drug plans and their own market power, the potential for large increases in prices paid is quite limited. This would likely only occur where there is some sort of mix shift or other extraordinary event. A fixed percentage cap is arbitrary and not appropriate to an industry marked by constant price changes due to changes in mix shift and events outside the patentee's control (e.g. new contracts, provincial government interventions, etc.). In any case, the PMPRB has the authority to deal with such situations if there is a substantiated consumer complaint.

The proposed Option 2, without the cap, is a rational approach to price regulation particularly given the rapidly changing pricing world. It permits patentees the flexibility they need to compete while maintaining consumer protection. In fact, this option will enhance competition since there is no disincentive to offer large, time limited discounts. Since it sets the maximum price for the medicine in a specific dosage form and strength, and is not the actual price charged by the patentee, it can be published and used as a benchmark by any manufacturer selling that medicine.