BROGAN INC.

Health Care Data, Research and Consulting

Sylvie Dupont
Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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May 9, 2005

By Fax: 952-7626

Dear Ms. Dupont:

Please consider this a submission from Brogan Inc. in response to the PMPRB Discussion Paper on Price Increases of Patented Medicines published in March 2005. Our comments deal with the policy, legal, constitutional and practical issues that should be resolved before any discussion about the form of further price restrictions can commence.

As you know, I was the chief policy advisor on the pharmaceutical patent issue leading up to the 1987 Patent Act amendments that resulted in the creation of the PMPRB. Moreover, I was responsible for the drafting of the PMPRB Regulations, implementing the legislation as it pertained to the PMPRB and drafting the first series of PMPRB Guidelines. The comments below are based on that knowledge and experience along with 15 years of advising Canadian pharmaceutical companies and governments on economic, pricing and market access issues.

The Patent Act amendments of 1987 were based on the need to ensure stronger intellectual property protection. The Minister of Consumer and Corporate Affairs was very clear that the main purpose for changing the Patent Act was to stimulate investment including research and development spending in Canada. This, along with the fact that the PMPRB mandate is included in legislation that is an industrial development policy tool, reminds us that Parliament did not intend on legislating a prices control mechanism or anything else that would discourage industrial growth. It is interesting to note that the Discussion Paper uses a single quote from a ministerial statement to justify the possible modification of the PMPRB Guidelines on price increases. However, a more complete analysis of the policy behind Bill C-22 would reach another conclusion.

The proposed frameworks contained in the Discussion Paper take the PMPRB in a direction not contemplated by Parliament. These changes would constitute price controls. If there is justification for a price control mandate, it is up to Parliament to change the legislation.

The reason the PMPRB mandate is within the Patent Act in the first place is the constitutional division of federal and provincial responsibilities. This was a fundamental consideration throughout the drafting of the 1987 legislation, the associated regulations and PMPRB Guidelines. Nothing has changed since 1987. We suggest the constitutionality of introducing federal price control regulations be resolved in public before attempting to define the details of a price control system.

It is clear that the PMPRB is concerned that inflationary price increases may result in prices which should be deemed excessive under the PMPRB Guidelines. The Discussion Paper contains no evidence that supports this position and that would warrant substantive punitive changes for the brand and generic pharmaceutical industries.

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The discussion paper refers to concerns about the possibility of drug shortages in Canada and price hikes of Canadian prices to the levels in the US. We have nothing to support the risk of drug shortages; however, further constraining Canadian prices will do nothing to remove the threat of drug shortages. It is also not clear how prices here could rise to US levels. Competitive forces in Canada make US price levels unrealistic, even in the long run. In addition, PMPRB rules now in place would prevent this.

The Discussion Paper also attempts to use the fact that drug spending is rising to rationalize further price controls. A number of studies, including the PMPRB study that replicates earlier work, have demonstrated that price increases have almost nothing to do with higher expenditures. While it is not clear what the relevance higher drug spending has for the PMPRB, it would be more useful had the paper included all of the evidence. Even prior to the implementation of the more stringent PMPRB CPI rules in 1994, price increases were not a factor in this regard.

Finally, international price comparisons are useful to a point. However, these comparisons when used to affect the well-being of the pharmaceutical industry, have to be put into the perspective of each of the countries. Such comparisons are informative but time-consuming and difficult to produce. However, without understanding market access, tax, drug approval systems, competitive pressures, standards of living etc. the relative price levels or levels of price change in different countries for a basket of drugs is not particularly enlightening.

In conclusion, we suggest the proposals contained in the Discussion Paper are not necessary and will not accomplish any of the goals stated in the paper. At very least, these proposals lack the foundation of legal and constitutional authority. Finally, we would suggest that there has to be substantially more evidence that price increases are a threat, particularly given the harm that the proposed changes would inflict on the Canadian pharmaceutical industry.

Sincerely,

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President

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