

October 22, 2007

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

**Re: Proposed Amendments to the Patented Medicines Regulations, 1994
announced on October 6, 2007**

Dear Ms. Dupont:

Please accept this letter as GlaxoSmithKline's (GSK) support of the submissions from *Canada's Research-Based Pharmaceutical Companies (Rx&D)* and BIOTECanada, in response to the proposed amendments announced on October 6, 2007.

GSK is a leading research-based pharmaceutical and vaccines company that strives to enhance the health and quality of life for patients in Canada and around the world. With over 3,300 employees across the country and manufacturing approximately \$2 billion worth of medicines in Canada each year - 25 percent of total Canadian pharmaceutical manufacturing output - it is also a key driver of Canada's knowledge-based economy. These contributions are all made possible by some \$200 million that GSK invests each year in research and development in Canada.

As outlined to the Board in the past, GSK has a number of concerns with the current pricing guidelines given their real impact both on our ability to compete internationally for research mandates and to bring innovative health care to Canadians.

In addition to the points outlined in the attached submissions, the Board's proposed amendments to the Average Price Calculation are of most concern to GSK. GSK believes that the proposed changes are unnecessarily burdensome, and do not provide real benefit to the PMPRB, patentees or, more importantly, Canadian patients. In fact, such changes may have the unintended impact of discouraging patentees from offering benefit programs to Canadians who need them, and most certainly will create significant paperwork and additional costs and hurdles to patentees.

Lastly, these proposed regulatory changes and the amendments to the Board's guidelines continue to be treated by the Board as parallel and distinct; GSK feels strongly that they are interrelated and must be managed together given their broader impact.

We believe that these and further actions by the PMPRB will only serve to make Canada's innovation environment less competitive and prevent Canadians from getting access to the medicines they need. We are especially concerned that the proposed changes come at a time when the government is aggressively - and laudably - seeking to enhance Canada's competitiveness and regulatory efficiencies through both Advantage Canada and its Science & Technology Strategy entitled *Mobilizing Science and Technology to Canada's Advantage*.

Yours truly,



Paul N. Lucas
President & CEO

CC:

The Hon. Tony Clement, P.C., M.P.
Minister of Health
0916A Brooke Claxton Building, 16th Floor Tunney's Pasture
Ottawa, Ontario K1A 0K9

The Hon. Jim Prentice, P.C., M.P.
Minister of Industry
235 Queen St.
Ottawa, ON K1A 0H5

Russell Williams, President, *Canada's Research-Based Pharmaceutical Companies (Rx&D)*
55 Metcalfe Street, Suite 1220
Ottawa, Ontario K1P 6L5

Peter Brenders, President, BIOTECanada
130 Albert Street, Suite 420
Ottawa, Ontario
K1P 5G4