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Terry Creighton  
Vice President Government Relations

October 6, 2008

Dr. B. Benoit  
Chair, Patented Medicines Prices Review Board  
333 Laurier Avenue West, Ste 1400  
Box L40, Standard Life Centre  
Ottawa, Ontario  
K1P 1C1

BY EMAIL [sdupont@pmprb-cepmb.gc.ca](mailto:sdupont@pmprb-cepmb.gc.ca),

**RE: Notice and Comment on the Draft Revised Guidelines**

Dear Dr. Benoit:

Novopharm Ltd is pleased to provide comments to the PMPRB's draft Compendium issued for Notice and Comment on August 20, 2008. **We fully support and endorse the detailed response of the Canadian Generic Pharmaceutical Association (CGPA) and wish only to reinforce the issues raised in their submission.**

The PMPRB guidelines are designed to protect consumers from excessive monopoly prices and price increases. Applying the PMPRB regulations to generic products is the classic allegory of trying to fit a square peg into a round hole. Generic products, regardless of whether they have a patent or not, are not monopolistic and are sold into a highly competitive marketplace. Often there are 7 or 8 suppliers of the exact same medication, some with patents, others without, competing on price for business from pharmacy operators. We urge the Board of the PMPRB not to lose sight of the objectives for which the Regulations were established - to ensure that Canadians are protected from excessive prices for their medications due to patent protection. Forcing unnecessary reporting and monitoring of generic prices will have no impact on achieving these goals.

There are enormous differences between brand and generic pricing regimes in Canada. Generic products provide great value to Canadian patients and drug plan payers. At introduction, generics in Canada are priced below their brand counterparts whose prices, in turn, are regulated through the PMPRB. Actual transaction prices can fluctuate greatly depending on market conditions. Some provinces regulate reimbursement levels relative to brand prices or only list products that provide great savings. Generics operate in a highly competitive environment and patients and government are the beneficiaries of this price competition.

In general, we support the recommendations made to the PMPRB Board by the Joint Working Group on Generics which are described, although somewhat altered, in the Notice and Comment. We continue to urge the PMPRB to support the logical conclusion that because generic prices are necessarily lower than brand products, due to both competitive forces and provincial regulations, as long as the brand product price is not excessive, neither is the generic price. In particular international prices of generic medicines are not relevant to the determination of whether Canadian generic prices are excessive. The recommendation to "waive the Golden Rule" with respect to international price comparisons is a logical and appropriate response. We believe this should also include products for which no brand is currently marketed in Canada. The application of the international pricing rule to one generic patented product would have no impact on non patented products. The PMPRB can not regulate overall domestic generic prices through the arbitrary application of the Act.

We would like to encourage the Board to adapt the Guidelines for generics in a way that is reasonable and imposes the minimum regulatory burden under your discretion. We appreciate the opportunity to have input to this process.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Creighton". The signature is written in a cursive, flowing style.

Terry Creighton  
VP Government Affairs