

APOTEX

ADVANCING GENERICS

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VIA E-mail c/o Barb Ouellet (bouellet@pmprb-cepmb.gc.ca)
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From the desk of:
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Dr. Brien G. Benoit, Chairperson
Patented Medicine Prices Review Board (PMPRB)
Box L40, Standard Life Centre
333 Laurier Avenue West, Ste 1400
Ottawa, ON K1P 1C1

Dear Dr. Benoit:

Apotex is pleased to provide comments to the PMPRB's draft Compendium issued for Notice and Comment on August 20, 2008. Apotex fully supports the response of the Canadian Generic Pharmaceutical Association.

Generic companies were never meant to benefit from the amendments to the Patent Act that extended patent protection for brand medicines. Generic patented medicines are an anomaly, as they always operate within a competitive market. Irrespective of whether generic patented medicines fall under the PMPRB jurisdiction as understood by the Patent Act (and Apotex does not necessarily agree that PMPRB has such jurisdiction), notwithstanding the current PMPRB Guidelines are not appropriate for generic medicines and would hinder competition in the Canadian pharmaceutical market by creating a two-tier system where only some generics in the same market are regulated. For example, in a multi-source generic market wherein only some of the generic medicines are patented, PMPRB creates arbitrary price controls over the patented generic medicines and whereas PMPRB has no jurisdiction over the unpatented ones; irrespective that obviously in this case the patent confers no benefit to the patentee and all generic competitors are in a competitive pricing market. The unpatented generic medicines are price uncontrolled, whereas the patented ones are; but the patentee gets no benefit of the patent.

Generic medicines are priced well below their brand equivalents. Moreover, generic prices are unrelated to consumer retail prices. Therefore, the mandate of the PMPRB to ensure that prices are not excessive and to protect consumer interests, are not achieved by regulating the prices of generic patented medicines according to the Guidelines. Additionally, the generic industry largely operates at a domestic level, and as such, international prices of generic medicines are not relevant to the determination of whether Canadian generic prices are excessive.

We thank the Board for engaging with the generic industry in the process of adapting Guidelines to recognize generic patentees' needs, and hope that the Board will persevere in its efforts to impose minimal regulatory burden on the generic industry and Board Staff.

Sincerely,

APOTEX INC.



Shashank Upadhye
VP, Global Intellectual Property