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Ms. Sylvie Dupont
Secretary to the Board,
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, 14th Floor
Ottawa, Ontario
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Re: Notice & Comment

Dear Ms. Dupont,

GlaxoSmithKline is pleased to respond to the PMPRB's Notice & Comment document of August 20, 2008, Draft Revised Excessive Price Guidelines.

GSK has been actively involved in the development of the submissions on this matter made by *Canada's Research-Based Pharmaceutical Companies (Rx&D)* and we wish to clearly state our full support of both the Rx&D response on this issue, as outlined in Mr. Russell Williams' letter of September 30, 2008 to Dr. Brian Benoit, as well as the appended Rx&D Technical Submission to the PMPRB.

GSK is deeply concerned that the PMPRB's hasty imposition of the proposed *Draft Revised Excessive Price Guidelines* following a flawed consultation process reflects a complete departure from the Board's mandate.

The PMPRB was established in the amendment of the *Patent Act* under Bill C-22 which limited compulsory licensing of pharmaceuticals. Consistent with C-22's objective of increasing investment in R & D in Canada, the role of the PMPRB in this context was clearly to protect the public interest by acting as a safeguard against *excessive prices.*

While the subsequent Bill C-91, which abolished compulsory licensing in order to align Canadian intellectual property protection for pharmaceuticals with international standards, further enhanced the Board's powers, the PMPRB's mandate remained unchanged:

- To ensure that prices paid by Canadians were *not excessive* in relation to prices paid in the seven countries named in the regulations,
- To monitor and report on pharmaceutical price trends, and
- To monitor and report on the R & D performance of patentees.

It is important to remember that the Board was established under the *Patent Act* to ensure that Canadian pharmaceutical prices are "not excessive". The creation of a price control regime for drugs was neither the purpose nor intent of Bills C-22 or C-91. While some non-industry stakeholders may imagine otherwise, the role of the PMPRB was never to guarantee that Canadians have the lowest international price.

Given that the proposed *Draft Revised Excessive Price Guidelines* represents a dramatic change of direction towards outright price control, we submit that they are contrary to the PMPRB's mandate, as outlined in the *Patent Act*.

In fact, the successful implementation of the Board's mission and mandate has always been dependent on the voluntary compliance of patentees with the existing Guidelines published by the PMPRB. In order to support voluntary compliance, the Guidelines must continue to be clearly aligned to the *Patent Act* and sufficiently straightforward to enable patentees to commercialize their discoveries by setting prices with a high degree of confidence that they will be deemed to be non-excessive in most circumstances.

We support the Rx&D technical submission, which clearly shows that the proposed changes add immeasurably to the complexity of the Guidelines without any visibly productive benefit. Proposals such as the price in any market proposal, the international therapeutic class comparison, and the proposal to alter the PMPRB's role to determine levels of therapeutic improvement further undermine the confidence in the regulatory framework which patentees need to bring their medicines to market in an orderly way.

Further, the draft proposals on re-setting MNE's, on exchange rates where new provisions call for price reductions as result of currency fluctuations, and the proposed methodologies for de-linking the MNE and ATP will also add considerable complexity to an already difficult compliance process for patentees.

Unfortunately, the proposed draft Guidelines only indicate that the Board is determined to make its processes more complex and opaque, at a time when Governments aim to be more straightforward and transparent. In fact, these proposals will inevitably result in more issues being referred to the Board, a slower price review process, more uncertainty and eventually more non-productive and costly hearings. The draft Guidelines will only transform the PMPRB into a regulatory bottleneck in which voluntary compliance by patentees will be increasingly difficult and expensive, with an exponentially increasing number of medicines "subject to investigation".

We strongly urge the PMPRB to defer the adoption of the proposed Guidelines. We call on the Board to work with industry to determine a way forward which is aligned with the broader Government policy objectives of containing and streamlining the regulatory burden on productive sectors of the Canadian economy. Without such an approach, our industry will be unable to continue to attract investment and compete in a global economy.

GlaxoSmithKline wishes to thank the Board for the opportunity to comment on these proposals and we hope that in this instance, the concerns of the innovative pharmaceutical industry will be clearly heard and considered.

Sincerely,

Paul Lucas
President & CEO
GlaxoSmithKline Inc.