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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 March 25, 2009, *Draft Revised Excessive Price Guidelines*.

GSK has been actively involved in the development of the submissions made by Canada's Research-Based Pharmaceutical Companies (Rx&D) on this matter, and we wish to go on record as fully supporting the Rx&D response. This position has been clearly outlined in Mr. Russell Williams' letter to Dr. Brian Benoit, as well as the appended Rx&D Technical Submission to the PMPRB.

GSK continues to be deeply concerned that the PMPRB's imposition of new and/or revised Excessive Price Guidelines is not reflective of the Board's mandate, and appears to be at odds with the intent of the Patent Act which created the PMPRB. We feel we must remind the Board that the creation of a price control regime for drugs was not the purpose of C-22 or C-91, and that an undefined advocacy for consumer interests and the national health care system are not part of the PMPRB's mandate under the Patent Act.

The successful implementation of the Board's mission and mandate is dependent on the voluntary compliance of patentees. With this premise in mind, Guidelines must be clear and transparent so that companies are enabled to commercialize their discoveries and set appropriate prices.

Throughout the revision process the Board must not lose sight of the fundamental principle that the Guidelines are administrative tools which strictly bind only Board staff in determining whether prices appear to be excessive. The Guidelines are not binding on the Board or patentees, and as such, must avoid excessive rigidity and remain sufficiently straightforward to ensure that the regulatory process is efficient and not overwhelmed with costly and time consuming conflicts over technical issues.

The Rx&D Technical Submission demonstrates that many of the proposed revisions will reduce transparency, create new rigidity, and result in an increased regulatory and administrative burden. The lack of clear language in many of the proposed revisions will

only add to this burden. For example, the description of prices as "sufficiently close to the NEAP", or the comparison of a new medicine to the lower-priced "superior product" is unclear, and needlessly adds to the complexity of the Guidelines.

Additionally, on Any Market Price Reviews the proposed changes introduce a new level of complexity which will increase the regulatory and administrative burden for patentees while decreasing transparency for other stakeholders. Under the proposed guideline for example, patentees will have to monitor and track 17 NEAPs per product versus the current one ATP per product. With this change, it is unclear how Any Market Price Reviews will actually be conducted, or how excessive revenues will be calculated. As well, there is no transparency as to what criteria will be used to determine the "appearance' of an excessive price, or what constitutes a legitimate complaint. What is clear is that the implications of, and the need for, this proposed Guideline change are not sufficiently understood to proceed to implementation in 2009 or 2010.

GSK strongly endorses the Rx&D position that these proposed changes not be implemented in the middle of the 2009 reporting period. We believe that revision of the Guidelines requires more work to ensure that changes will ultimately enhance compliance and improve transparency. It is our hope and intent to continue to work with the Board to improve the Guidelines in a way which is aligned with the broader Government policy objectives of containing and streamlining the regulatory burden.

GlaxoSmithKline wishes to thank the Board for the opportunity to comment on these proposals.

Sincerely,

Paul Lucas
President & CEO
GlaxoSmithKline Inc.