GLAXOSMITHKLINE

SUBMISSION TO THE

PATENTED MEDICINE PRICES REVIEW BOARD

ON ITS DISCUSSION PAPER OF JANUARY 31, 2008

Options for Possible Changes to the:
Patented Medicines Regulations, 1994; and the
Excessive Price Guidelines

February 29, 2008

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 to protect the public interest by acting as a safeguard against *excessive prices*, which might hypothetically result from extended patent protection

Its powers were enhanced in the subsequent Bill C-91 which abolished compulsory licensing with the objective of aligning Canadian intellectual property protection for pharmaceuticals with standards then being developed for the W.T.O. However, 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
- To monitor and report on the R & D performance of patentees.

It is important to remember that creation of a price control regime for drugs was not the purpose of C-22 or C-91 and not part of the PMPRB's mandate – in fact, the Board's policy allows prices to increase in line with the Consumer Price Index (CPI).

Implementation of the Board's mandate that Canadian prices should not be excessive is largely dependant on the voluntary compliance of patentees with the Guidelines published by the PMPRB. Voluntary compliance requires guideline policies that are clearly linked to the factors in the Patent Act. Guidelines must also be sufficiently transparent and aligned with existing commercial practices to enable patentees to set prices with a high degree of confidence that they will not be facing allegations of excessive pricing purely on the basis of obscure technicalities and needlessly complex procedures. The Board needs to ask itself whether any proposed change which increases the complexity of the Guidelines also increases the risks of unintended consequences and of undermining compliance.

GSK underlines its endorsement of the policy points made in the Rx&D Submission on the Discussion Paper.

We also wish to provide some additional comments on some key points which the Rx&D Submission deliberately makes at a high level rather than in detail. This is in line with our comments above urging the Board to consider carefully the risks of unintended consequences and the undermining of compliance stemming from the increased regulatory burden imposed by inadequately considered policy changes. Care should be taken to ensure that changes to PMPRB policies and guidelines do not conflict with the intent of federal initiatives to simplify and reduce the impact of regulation.

An example of a Guideline change that can have unintended consequences is the proposal that the price in any market can not exceed the MNE. Fully applied to all patented products this change may have the potential to put at risk industry practices such as extending contract pricing to the hospital sector. Discounted hospital contract prices when averaged with list prices charged to other trade classes reduce the MNE to levels below the prices actually charged to drugstores and wholesalers. It will result in a patchwork of various markets priced above MNE depending on which provincial hospital buying groups enter into contracts in a given period. This means that the PMPRB could inadvertently create an incentive for patentees to stop offering lower prices to hospitals simply in order to ensure compliance with a new Guideline.

.
Hospitals are a clear example of a customer class that can suffer unintended consequences from a proposed Guideline change, but the Board should be reminded that there are also classes of products that could be adversely affected

Vaccines are an example of a unique class of product. Like OTC's, vaccines are generally non-prescription products. They are sold in a highly competitive environment under different terms, at different prices, to different trade classes or markets. Unlike prescription medicines, a major portion of vaccines sales are made under Federal and Provincial government contracts which aim to secure a supply of competitively priced immunizations for Canadians. But those contracts that provide governments with competitive prices also create volatility in average selling prices as sales shift from one trade class to another when contracts are won and lost. That volatility creates regulatory issues for the manufacturer as the variability of average selling price encounters an artificial construct called the MNE. The Board should consider whether increasing the regulatory burden for vaccines could have as an unintended consequence an increased burden for manufacturers in securing supplies for Canada in the face of supply constraints caused by increasing demand from other jurisdictions globally.

GSK believes that the PMPRB should treat vaccines as a unique class of product and should in fact consider deregulating vaccines as was done with veterinary medicines and as is proposed for OTC's.

GSK appreciates the opportunity to bring our views forward, and we trust that they will be given due consideration in the context of our full support of the positions outlined in the industry position submitted by Rx&D.