

January 14, 2016



Guillaume Couillard
Director, Board Secretariat, Communications and Strategic Planning
Patented Medicine Prices Review Board
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Re: Notice & Comment

Dear Mr. Couillard,

GlaxoSmithKline is pleased to respond to the PMPRB's Notice and Comment relating to the Reasonable Relationship Test Amendment and the List Price Relative to MAPP Verification Amendment.

1. Reasonable Relationship Test (Schedule 4) Amendment

GlaxoSmithKline would support this amendment with the following clarifications:

- What time period would be used for the N-ATP comparison?
- If a price increase is taken on the existing DIN during the applicable time period, will the N-ATP be adjusted for comparison purposes?
- What if N-ATP includes benefits and thus, is lower than the lowest of the public sources (for example, N-ATP includes free goods associated with a patient support program)? Would the PMPRB consider using the lowest of the public sources in these scenarios?

2. List Price Relative to MAPP Verification Amendment

GlaxoSmithKline is in favor of this amendment subject to the following questions/comments:

- The CD&H price source usually includes wholesaler mark-up fees. Will the PMPRB be making allowances for this?
- The list price decrease to re-align to MAPP at time of introductory price review should not impact the IBP.
- Will patentees be given a pre-determined amount of time to implement the list price decrease, as applicable?
- If list price is greater than MAPP, will this generate excess revenues even if N-ATP is in compliance?

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

Sincerely,

Katherine Miles
Pricing Analyst
GlaxoSmithKline