



January 29, 2016

Mr. Guillaume Couillard Director, Board
Secretariat Communications and Strategic Planning
Patented Medicine Prices Review Board (PMPRB)
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Re: AstraZeneca Canada Inc. response to PMPRB Guidelines Notice & Comment

Dear Mr. Couillard:

On December 4th, 2015 the PMPRB issued a Notice and Comment period and proposed changes to the Compendium of Policies, Guidelines and Procedures (the Guidelines) that became effective as of January 1, 2016.

AstraZeneca Canada Inc. fully supports the response and position submitted by Innovative Medicines Canada (IMC) to the PMPRB as part of your Notice and Comment period.

We are disappointed by the manner in which the PMPRB has introduced changes to the Guidelines without advance consultation. This lack of consultation is inconsistent with the spirit of the working relationship and co-operation that Canadian pharmaceutical patentees and the PMPRB have shared since its inception.

The proposed change to the Reasonable Relationship Test and resulting new methodology is fraught with inconsistency as articulated in IMC's submission. Clearly, the PMPRB should undertake appropriate consultation with IMC and manufacturers to understand the impact on patentees.

Furthermore, we believe that it is important for the PMPRB to understand the potential for unintended consequences that negatively impact the viability of introducing new innovations in Canada, and, most importantly any impact to Canadian patients.

In particular, AstraZeneca is deeply concerned and objects to the PMPRB's proposed change regarding the requirement whereby manufacturer list prices cannot be higher than the Maximum Average Potential Price (MAPP). It is our view that such action is well beyond the PMPRB's scope, mandate, and jurisdiction, which does not include regulation of manufacturer list prices. As such, we strongly urge the PMPRB to reconsider and abandon this proposed requirement altogether.

AstraZeneca Canada Inc. has always prided ourselves as being thought partners with policy makers and payers and believe strongly that solutions to complex matters are found through open and thoughtful consultations. As such, we encourage the PMPRB and Government of Canada, to reconsider the proposed changes and to seek an earnest approach to consultation process. The modifications put forward are significant and require a robust analysis and timely meaningful stakeholder response.

Sincerely,

Lisa Marsden
Vice President, Patient Access and Established Brands

cc: Ms. Mary Catherine Lindberg, Chair
Mr. Doug Clark, Executive Director