AstraZeneca Canada Inc. • 1004 Middlegate Road • Mississauga • Ontario • Canada • L4Y 1M4
T: 905 277 7111 or 1 800 565 5877 • F: 905 270 3248 • www.astrazeneca.ca

October 25, 2016

Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

BY E-mail: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: **AstraZeneca Canada Inc. submission to PMPRB Guidelines Modernization: Rethinking the Guidelines**

Dear PMPRB:

AstraZeneca Canada would like to acknowledge the Patented Medicine Prices Review Board (PMPRB) for the opportunity to participate in the public consultation process regarding the *PMPRB Guidelines Modernization*.

We fully support Innovative Medicines Canada's (IMC's) submission to the PMPRB, which clearly articulates the innovative pharmaceutical industry's position and commentary on the *Discussion Paper*.

AstraZeneca has always prided itself as being a thought partner to policy makers and payers and believes strongly that solutions to complex matters are found through open and thoughtful consultations.

The possible Guideline reforms as outlined in the content and questions of the *Discussion Paper* may put forward significant changes to patentee's operating environment within the Canadian healthcare system. With this in mind, AstraZeneca believes that meaningful stakeholder consultation in the form of working groups is required to engage in the active dialogue necessary to adequately address the questions raised in the *Discussion Paper.*

The *Discussion Paper*, PMPRB's 2015 Annual Report, and PMPRB's outreach sessions with the pharmaceutical industry bring into question the interpretation of the PMPRB's own data, which is in fact, provided to the PMPRB by individual patentees. The PMPRB asserts that Canadian prices are "among the highest patented drug prices in the world" using OECD and other selective local and international data sets that serve to fuel the PMPRB's "relevance" agenda.

It should be noted to all stakeholders participating in the *PMPRB Guidelines Modernization* consultation that a pharmaceutical patentee's own data that is reported to the PMPRB, which informs the PMPRB's data, may yield a different view on the state of drug pricing in Canada.

Pharmaceutical patentees in Canada are required to report customer sales and pricing data for both single source (have a monopoly) and multisource (do not have a monopoly) patented drugs to the PMPRB. Typically, Canadian patentees do not lower the price of multisource patented drugs as the combined forces of generic competition and mandatory generic substitution at the provincial formulary and private payer level rapidly erode patented product sales revenue when the drug loses its monopoly.

This fact is a very important distinction when considering *PMPRB Guidelines Modernization*. The PMPRB itself cites that drugs that have a monopoly (single source) require their focus. As such, the PMPRB owes all stakeholders involved in this consultation an analysis on single source drugs introduced in Canada with a monopoly and where these drugs rank vs. PMPRB7 benchmark countries (France, Sweden, Switzerland, Germany, France, UK, and US).

For the purposes of this consultation, AstraZeneca believes that it may be in the best interest of all stakeholders to have an independent third party consulting firm validate both the PMPRB and IMC member data from the PMPRB7 benchmark on single source (have monopoly) drugs to enable all stakeholders to have grounded, well-informed, and un-biased view of Canadian drug prices.

We support adding a third party consulting firm to the *PMPRB's Guidelines Modernization* consultation as a fair and equitable way for all stakeholders to understand pricing data that is relevant to appropriately inform any future decisions that may be undertaken as a result of this public consultation.

The primary mandate of the PMPRB is to ensure that the ex-factory prices of patented medicines are not excessive, and to report on pharmaceutical trends of all medicines, and on R&D spending by pharmaceutical patentees.

AstraZeneca is confident that an independent third party validation of the PMPRB's data for single source drugs will yield results that validate the PMPRB's fulfilment of its role and relevance in protecting Canadians from "excessive" drug ceiling prices as defined under the *Patent Act*.

AstraZeneca does not believe that the PMPRB is the appropriate agency to decide upon the affordability of medicines in Canada. The PMPRB is not accountable for spending decisions, does not select drugs for reimbursement, does not pay for medicines, and does not have visibility into drug and health budgets. The Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en service sociaux (INESSS), and the pan-Canadian Pharmaceutical Alliance (pCPA) as well as individual provinces and territories are already charged with these roles, and better placed to work with and/or negotiate with the industry to answer these questions.

At AstraZeneca, we believe that "science" is at the centre of everything we do. Advances in science have transformed the treatment of disease in Canada. Canadian research and development and research partnerships create significant knowledge-based employment opportunities in Canada.

AstraZeneca has significantly expanded our Canadian clinical study footprint. We are leading more than 60 clinical studies involving approximately 3,500 patients, and have tripled the size of our Clinical Study team to more than 120 people.

We are committed to Canadian research and development and collaborative approaches that find solutions that first and foremost benefit patients and ensure a sustainable way forward for payers, the health care system, the economy, and industry. For example, in 2015, AstraZeneca invested more than $54 million in Canadian health sciences research. Among some of the landmark research partnerships we have recently entered into include:

- A $1 million donation to the **Banting & Best Diabetes Centre** (BBDC), Canada's leading centre of excellence for innovation in diabetes research, education and clinical care. The investment was directed at projects aimed at improving care for patients living with diabetes.
- A $500,000 donation to the **FORGE AHEAD** *(TransFORmation of IndiGEnous PrimAry HEAlthcare Delivery)*, a five-year program led by Dr. Stewart Harris at Western University that is aimed at improving diabetes care for Canada's First Nations communities, where diabetes prevalence is much higher than the national average.
- A commitment of $1 million to **Stand Up to Cancer Canada**, supporting Canadian-led collaborative research aimed at meaningful advancers in cancer treatment.
- A $35 million commitment to help create the **NEOMED Institute**, in collaboration with the Quebec Government, a Quebec-based non-profit organization that is advancing leading-edge health sciences R&D.

These investments are dependent on a predictable, sustainable and internationally competitive pricing environment in Canada. While these investments may not be interpreted by PMPRB as scientific research and experimental development (SR&ED) eligible pharmaceutical R&D investments, they are invaluable in supporting the Life Sciences sector in Canada and a knowledge-based economy.

An updated method for defining and accounting for Canadian pharmaceutical R&D investment is urgently needed. Furthermore, we believe the PMPRB, the Government of Canada, and all stakeholders must understand the potential for the unintended consequences that could be driven by an interpretation of the PMPRB's and patentee's data. Such an interpretation could negatively impact the viability of introducing new innovative medicines in Canada impacting Canadian patients and future pharmaceutical R&D investment in Canada.

Sincerely,

Mark Findlay
Vice President, Patient Access and Established Brands