February 12, 2021

AstraZeneca Canada Inc.
1004 Middlegate Road, Suite 5000
Mississauga, Ontario, L4Y 1M4, Canada
T: +905-277-7111
F: +905-270-3248
www.astrazeneca.ca

Dr. Mitchell Levine
Chair, Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa ON, K1P 1C1

RE: January 2021 Notice and Comment - On the change to the definition of Gap medicines and the timeline for compliance

Dear Dr. Levine,

On behalf of AstraZeneca Canada Inc. (AstraZeneca), thank you for the opportunity to provide input on the PMPRB's proposed amendments to its Guidelines resulting from the federal government's decision to delay the coming-into-force date of the amendments to the *Patented Medicines Regulations* (the regulations) by a further six months, from January 1, 2021 to July 1, 2021.

AstraZeneca has actively participated in all relevant consultations regarding the reform of the PMPRB including through our industry associations, Innovative Medicines Canada and BIOTECanada. This submission is complementary to those made by our industry associations.

In terms of our footprint in Canada, AstraZeneca employs more than 875 Canadians who work to research, develop and commercialize innovative medicines across our main therapeutic areas of cardiovascular, renal and metabolic diseases; oncology; and respiratory and immunology illnesses. In 2019, AstraZeneca invested more than $145 million in Canadian health sciences research in our core therapeutic areas.

Before addressing the PMPRB's proposed amendments – specifically the proposed new transition period, which is the most problematic aspect of the January 2021 Notice – we would like to take the opportunity to reiterate some of our overarching concerns regarding the new pricing regime, and the PMPRB's proposed approach to operationalizing the regulations.

AstraZeneca is now entering an exciting new period of research, innovation and unprecedented scientific advances. We have numerous ground-breaking new treatments across our therapeutic areas that we are hoping to bring to Canadians as soon as possible. AstraZeneca has also been very involved in the fight against COVID-19. As you may know, our vaccine is on track to being approved by Health Canada in the coming days. We are committed to making this vaccine widely accessible to Canadians and countries around the world at no profit during the pandemic.[1]

[1] https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html

However, the PMPRB changes have made it increasingly challenging for us as a Canadian affiliate to make a compelling business case to our global headquarters to make Canada a priority launch country for some of these new ground-breaking medical innovations given the uncertainties and unpredictable price reductions mandated by the new rules, while continuing to use a misleading, 30-year-old definition of R&D.

For decades, AstraZeneca has been investing in new, more collaborative models of R&D partnerships with Canadian universities, hospitals, centres of excellence and early stage biopharmaceutical companies. We are also investing hundreds of millions of dollars in Canadian-led global Oncology and Immuno-oncology clinical trials, as well as new areas of science including Real World Evidence, Epidemiology, Pharmacoepidemiology, Health Economics, and Outcomes research – all areas of research and development that are well within the scope of OECD and Statistics Canada definitions of R&D.

Our medicines will be adversely affected by one or more of the many proposed changes, ranging from the country comparisons to the continued reflection of the new economic factors with uncertainty in how they will be applied. Ultimately, the PMPRB changes are adding another potentially insurmountable barrier at the top of an already complicated, costly and uncertain commercialization pathway, that will ultimately delay patient access to some of these important medical innovations and reduce health research in the country.[2][3][4]

The new rules have also come at a very challenging time as our country struggles to respond to the COVID-19 crisis. The federal government's decision to exempt COVID-19 therapeutics from being subject to the new pricing rules clearly demonstrates that the rules would impact access as outlined above. Unfortunately, the PMPRB still continues to experiment with novel and uncertain approaches to price regulation, at a time when new research, innovation and medicines and vaccines are needed the most. This is a time for PMPRB and the Federal government to come together with the innovative biopharmaceutical industry to find solutions that will truly benefit the health of Canadians and ensure a vibrant life sciences sector to help drive post-pandemic economic recovery.

Of note, in this increasingly challenging context, the PMPRB should have, at a minimum, changed its guidelines to remove all references to the Maximum Rebated Price (MRP) and the related

[2] IQVIA, June 2020, New Medicine Launches: Canada in a Global Context: "Canada may be losing its status as a top global destination for new medicine launches": https://lifesciencesontario.ca/canada-may-be-losing-its-status-as-a-top-global-destination-for-new-medicine-launches/

[3] Life Sciences Ontario, January 2021, "New survey data: Federal drug pricing regulations are already stopping what Canadians want: access to new medicines as soon as possible": https://lifesciencesontario.ca/new-survey-data-federal-drug-pricing-regulations-are-already-stopping-what-canadians-wantaccess-to-new-medicines-as-soon-as-possible/

[4] Nigel Rawson, February 2021, Canadian Health Policy, "Clinical Trials in Canada: Worrying Signs that PMPRB Changes will Impact Research Investment": https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada--worrying-signs-that-pmprb-changes-will-impact-research-investment.html

economic factors, given they rely on the requirement for companies to share net prices with the PMPRB, which has recently been deemed invalid by two courts. Changes should have included guidance to patentees and board staff that the PMPRB will not apply the MRP and economic factors even in the context of investigations pending the outcome of the appeals of the court decisions.

Regarding changes proposed in the January 2021 Notice more specifically, we are extremely concerned about the PMPRB's proposal to cut the Guidelines transition period in half, from two reporting periods (12 months) as outlined in the October 2020 Guidelines to just one (6 months) as proposed in the Notice.

Not only is there no rationale provided for the proposed change, but this proposal also goes directly against the spirit and intent of the federal government's decision to delay the coming-into-force date of the regulations by six months – namely to allow companies to remain focused on responding to the COVID-19 pandemic, while providing more time for patentees to familiarize themselves with and prepare for the new reporting obligations. If the transition period is reduced to just one reporting period, patentees will face unnecessary administrative burden and compliance challenges that will detract attention and resources away from responding to the pandemic.

Six months is simply not a reasonable amount of time for companies to address the many challenges of compliance, including obtaining global approvals, communicating with customers, amending agreements and contracts, and managing potential disruptions up and down the supply chain, while also focusing on bringing lifesaving Covid-19 vaccines and treatments to Canadians.

For this reason, AstraZeneca strongly recommends, at a minimum, a twelve-month transition period from the entry into force date of the regulations as previously proposed in the October 2020 PMPRB Guidelines document.

Thank you for considering our submission. If you have any questions, please do not hesitate to contact me.

Yours Sincerely,

Jane Chung
President, AstraZeneca Canada