February 14, 2020

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1
Submitted electronically to PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: PMPRB DRAFT Guidelines

Dear Board Members,

As advocates representing millions of Canadian patients, the Alliance for Safe Biologic Medicines (ASBM) appreciates the opportunity to comment on the PMPRB's new Draft Guidelines. ASBM is a global alliance of patient advocacy organizations and physician societies, working to promote patient-centered biosimilar policies worldwide. The Gastrointestinal Society is one of our leading Canadian members, and represents as many as 6 million Canadians with irritable bowel syndrome (IBS), more than 9 million with functional dyspepsia, as many as 8 million with chronic acid reflux (GERD), and an additional 233,000 suffering from chronic inflammatory bowel disease (Crohn's and ulcerative colitis).

We are keenly aware of the importance to these patients we represent of improving access to new and innovative life-improving and life-extending therapies by ensuring affordability of medicines. However, pricing policies alone do not guarantee access; other factors contribute as well. Ensuring that new medicines available to patients in other advanced countries are launched in Canada as well is among these key factors.

It is our view that while well-intentioned, the new Draft Guidelines have a strong potential to upset this critical balance, by disincentivizing manufacturer investment in product launches and dissuading applications or subsequent indications in Canada thereby jeopardizing, rather than promoting, patient access to such therapies.

In its budget for 2017, the Canadian Government laid out a vision for Canada to become a global leader in innovation. Pursuant to this objective, the Government established an Economic Strategy Table (EST) for the Health Biosciences Sector, which published its recommendations in September 2018. These set the goal of "doubling the size of the sector by 2025 and [becoming] a top-three global hub by leveraging and advancing innovative technologies; attracting and retaining capital, skills, and talent; and ensuring a vibrant ecosystem that will unleash the full potential of the sector and lead to improved health outcomes".

While in attendance at the Drug Information Association (DIA) Annual Canadian Meeting in November 2019, ASBM representatives heard Health Canada's Director of Scientific & Regulatory Affairs for Consumer Health Products, Kristin Willemsen, reiterate the importance of these objectives.

Among the obstacles identified by the government report were 1) Complex regulatory, reimbursement and procurement processes [that] impede the adoption of innovations, and 2) A risk-averse procurement culture [that] prioritizes short-term focus on cost rather than broader considerations of value.

Indeed, a recent survey from Life Sciences Ontario of 46 pharmaceutical executives revealed a unanimous belief that the PMPRB is pushing Canada in the opposite direction from what both the Government and patients want. Respondents universally expressed the belief that PMPRB Draft Guidelines would have negative impacts, including with regard to product launches and commercialization (97%), employment (97%), clinical research (91%), patient support programs (73%) and compassionate access programs (70%).

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Unfortunately, we may already be witnessing the unintended consequences of this policy. According to data from Health Canada, the number of new drugs submitted in has fallen sharply since the PMPRB Draft Guidelines were announced, with the 2019 figures representing a 44% drop from those in 2018, and a 30% drop from the 2016-2017 period.

We find these trends to be disconcerting and feel they warrant further investigation by PMPRB prior to implementing a policy which may have serious unintended negative consequences for patients.

While we do not support the decision to align the basket of countries from the former seven to the new eleven, the effects of this adjustment on lowering drug prices in Canada are not yet known. The further guideline details, however, are extreme, even draconian, and will likely result in diminished access to essential treatments for patients. **We urge you to wait to see the effects of the adjusted basket of countries and assess its success before taking any further steps.**

In summary, while affordability of medicines is a key component of improved access, so is their availability in the Canadian market. The patients we represent are not well-served if fewer of the newest medicines launch here relative to other advanced countries.

In light of these concerns and the Government's stated goal of protecting and promoting innovation as a means of ensuring improved patient outcomes, we respectfully urge the PMPRB to reconsider and re-examine its approach to ensure that pricing policies do not do Canada's patients a disservice by overprioritizing short-term cost considerations at the expense of long-term access to innovative medicines.

Thank you for the opportunity to comment on this important issue.

Sincerely,

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