



February 13, 2020

Patented Medicine Prices Review Board
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

By email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: Comments on PMPRB draft Guidelines

Otsuka Canada Pharmaceutical Inc (OCPI) thanks you for the opportunity to provide input to this phase of the consultation process regarding the proposed changes to the PMPRB Guidelines. We are members of Innovative Medicines Canada and are fully aligned with their submission on the draft Guidelines, but also wish to bring separate concerns affecting OCPI to your attention.

A key consideration for a Global Japanese pharmaceutical company to invest in Canada was Canada's well-established pharmaceutical environment, with its clear rules of engagement providing a fair and secure marketplace. In contrast, with the current status of the proposed PMPRB Guidelines change, and the many critical details which have yet to be clarified, we find ourselves facing a regulatory environment that is far from certain and appears arbitrary in some of its approaches.

Since choosing to invest in Canada in 2010, OCPI has brought Canadians innovation. That innovation included a first-in-disease treatment for Autosomal Dominant Polycystic Kidney Disease (ADPKD), which Canadians were the second in the world to access. In the field of mental health, OCPI has brought Canadians two innovative antipsychotic medications to help those who are among the most vulnerable in our society. Furthermore, OCPI has supported research in many areas including: research into the impact of psychotic relapses on brain function, the creation of an ADPKD registry to gather real world evidence with Canadian researchers and clinicians in this evolving field, and research which has provided a greater understanding of the impact of consistent antipsychotic treatment on improving hospital resource utilization in the Province of Quebec.¹

¹ AXIS Publication

As an innovative company, OCPI is eager to partner with a diverse array of stakeholders to find ways to bring treatments to market while considering the broader implications on overall sustainability, on public health and on continued development and innovation. It is with this intent that OCPI entered into discussions with a Global partner to bring innovative medications that address Canadian unmet needs in the field of nephrology.

The first medication from this new partnership has been received positively by Canadian health care practitioners as well as payors and resultant listing agreements have been signed with various Canadian governments. These listing agreements were predicated on mutual acceptance of the financial terms; however proposed changes to international price referencing may impact those agreements, calling into question the perceived stability and fairness of the Canadian regulatory environment. To address this, we believe that there needs to be a complete 'grandfathering' of existing products (i.e. the proposed new rules should not apply to existing agreements) in recognition of the investments and commitments that were made by both government and industry prior to the proposed changes to the PMPRB guidelines.

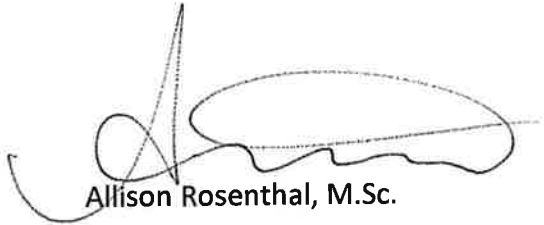
As a result of the proposed economic factors, and compounded by broad criteria for reassessment, the suggested changes do not allow an accurate assessment of allowable ceiling prices at launch or through the lifecycle of the product. Furthermore, the proposed guidelines are currently in draft form and many crucial details are missing. Our international partners have had many questions and have expressed concern at the changing regulations and their potential impact on planned future investment. To address this, the PMPRB needs to be transparent regarding the technical details of the proposed changes and to provide adequate time for stakeholders to assess their impact in advance of the new rules coming into force.

Concluding Remarks

From opening our doors in 2010 in Canada, OCPI has created more than 100 high-value positions across the country – all occupied by Canadian citizens. A key objective of ours is to continue to grow and invest in Canada. While building a business in Canada, OCPI has contributed to innovation, research and development in this country. OCPI has supported a number of studies, scientific publications and abstracts.

In reviewing the materials provided and presented by the PMPRB, it appears that much of the context for changing the guidelines is based on a few outliers. Otsuka Canada supports reform that improves health system sustainability; however, we do not believe that the proposed changes PMPRB guidelines will result in this outcome. Our position is that contractual agreements with government (i.e. public payors) that were executed before the proposed

guidelines change should be exempt from retroactive changes. Regarding new medications, greater clarity and full technical details of the proposed methodological changes are required from the PMPRB before meaningful assessments of the impact on future drug launches in Canada can be made. These changes need to take place prior to the finalization of the guidelines.

A handwritten signature in black ink, appearing to read 'Allison Rosenthal', with a large, sweeping flourish extending to the left.

Allison Rosenthal, M.Sc.

General Manager

Otsuka Canada Pharmaceutical Inc.