

Dr. Mitchell Levine
Chairperson
Mr. Douglas Clark
Executive Director
Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

August 4, 2020

cc: The Honourable Patty Hajdu, P.C., M.P., Minister of Health

RE: Feedback Submission on June 2020 PMPRB Draft Guidelines

Dear Dr. Levine and Mr. Clark:

Crohn's and Colitis Canada is pleased to offer comment on the recent *PMPRB Draft Guidelines*. We continue to support the requirement for meaningful patient engagement in all Canadian processes that affect the timely access to drug treatments for patients in our inflammatory bowel disease community.

It is acknowledged that the PMPRB, set up to ensure drug prices are not excessive, has achieved its mandate with drug prices in Canada continuing to be at the mid-range of countries in the current structure. This is corroborated with your own analysis. In 1987, when the PMPRB was created, other organizations including the Canadian Agency for Drugs and Technologies in Health, Institut national d'excellence en santé et services sociaux, pan-Canadian Pharmaceutical Alliance and the pending Canadian Drug Agency were not part of the Canadian drug review landscape. The changes other organizations have introduced (including rigorous clinical and cost-effectiveness review) necessitate a broader review of the place of PMPRB, and indeed whether PMPRB is an appropriate vehicle for the analysis proposed in the *Draft Guidelines*. The inadequate consultations on the *Draft Guidelines* have eliminated opportunity to consider the appropriate role of PMPRB, how the changes will impact patients across Canada, and how the new approach considers the ultimate mandate of the PMPRB. Pushing these changes through without collaborative consultation and consideration is not in the best interest of Canadians.

We continue to have concerns with the complexity of the *Draft Guidelines*, which appears to have increased with this second draft. Uncertainty exists with the impacts of the reform including potential for delays in setting price limits, access to new drugs, and clinical trials in Canada.

While Crohn's and Colitis Canada supports initiatives to manage drug budget expenditures, we believe that this goal should be achieved without affecting the health outcomes of patients in Canada. We urge you to pause and reset the *Guideline* development process to focus on core regulatory principles of feasibility, fairness, clarity, and predictability, and ensure that Canadians can access new medicines in a timeframe comparable to the present day. As others have opined, we would support moving ahead with application of the revised basket of comparator countries, given that this will provide price reductions that will satisfy the goal of improving medication affordability. Other aspects of the revised *Guidelines* are inherently complicated and present an unpredictable outcome for Canadians thus requiring further – collaborative and patient-centred – consultation.

Our review of the *PMPRB Draft Guidelines* is from the perspective of the many thousands of people in Canada living with Crohn's disease and colitis. We continue to strive to find the cures for these debilitating diseases and simultaneously support access to innovative treatment to improve the lives of people in our community. We are looking to the PMPRB to be a partner in achieving our goal to improve the health outcomes of people with Crohn's and colitis through fair and supportive health policy processes.

We would be pleased to contribute to a fulsome review and consultation and work with you to address the concerns we have presented.

Sincerely,



Mina Mawani
President and CEO
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ABOUT CROHN'S AND COLITIS CANADA Crohn's and Colitis Canada is the only national, volunteer-based charity focused on finding the cures for Crohn's disease and ulcerative colitis and improving the lives of children and adults affected by these diseases. We are one of the top two health charity funders of Crohn's and colitis research in the world and the largest nongovernmental funder in Canada. We are transforming the lives of people affected by Crohn's and colitis (the two main forms of inflammatory bowel disease) through research, patient programs, advocacy, and awareness.