



February 14, 2018

Karen Reynolds
Executive Director
Office of Pharmaceuticals Management Strategies
Strategic Policy Branch, Health Canada 10th Floor
Brooke Claxton Building, 70 Colombyne Driveway
Tunney's Pasture, Ottawa, Ontario K1A 0K9

By e-mail: PMR-Consultations-RMB@hc-sc.gc.ca

Re: Canada Gazette, Part I (CG1), December 2, 2017, Regulations Amending the Patented Medicines Regulations

Dear Ms. Reynolds,

Takeda Canada Inc. would like to acknowledge Health Canada for the opportunity to participate in the public consultation process regarding *Canada Gazette Part I, Regulations Amending the Patented Medicines Regulations dated December 2, 2017*.

Takeda Pharmaceutical Company Limited is a global, research and development-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda Canada, located in Oakville, Ontario, is the Canadian sales and marketing organization of Takeda Pharmaceutical Company Limited.

As a member of Innovative Medicines Canada (IMC) and BIOTEC Canada, Takeda Canada fully supports the submissions filed by both industry associations that clearly articulate the position and commentary regarding the CG1 regulatory proposals.

First and foremost, we acknowledge the concerns raised by Canadian patients through patient associations requesting more transparency and fulsome dialogue on the potential negative impact on patient access to new innovative medicines that Health Canada's proposed amendments may pose.

We believe that the CG1 regulatory proposals and specifically the proposed use of pharmacoeconomic analyses in combination with cost effectiveness thresholds will introduce an incremental level of complexity that is unwarranted, confusing, and not enforced in any other country. For this reason, we urge Health Canada to consider removal pharmacoeconomic considerations from its CG1 regulatory proposals.

We strongly encourage Health Canada to embrace and incorporate stakeholder input to develop collaborative options and alternative solutions to patented medicines price regulation with the view to maintaining a sustainable Canadian healthcare system where Canadians families can benefit from access to new innovative medicines.

If you have any questions regarding our feedback please reach out to Steven Popp, Director, Strategic Pricing & PLA by email at steven.popp@takeda.com or by telephone 905-465-4161.

Sincerely,

A handwritten signature in black ink, appearing to read "Kieran Leahy", written over a horizontal line.

Kieran Leahy
Interim General Manager