



June 21, 2021

Patented Medicine Prices Review Board (PMPRB)  
Box L40 Standard Life Centre  
333 Laurier Avenue West, Suite 1400  
Ottawa, Ontario, K1P 1C1

Submitted via Portal: <https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/consultation-guideline-monitoring-evaluation-plan.html>

**Takeda Canada Consultation Response: PMPRB Proposed Guideline Monitoring and Evaluation Plan**

Founded in Japan in 1781, Takeda operates in more than 80 countries worldwide, including Canada. More than a decade ago, Takeda made the strategic decision to become a specialty medicines company and today, we have evolved into the global leader in treatments for rare diseases.

Takeda Canada is pleased to offer comments on the consultation to monitor and evaluate the Patented Prices Medicines Review Board (PMPRB)'s regulatory guidelines. As members of both Innovative Medicines Canada and BIOTEC Canada, Takeda Canada supports the submissions made by both associations, and specifically, supports the call for a third-party reviewer to lead the monitoring and evaluation function of the PMPRB.

Over the past number of years, Takeda Canada has engaged at multiple points to be better engaged, informed and heard as part of the PMPRB's consultation processes.

Takeda Canada is challenged to substantively respond to the latest consultation from the PMPRB, with both the government and the PMPRB having yet to address existing concerns regarding the government's direction on the policy file as well as the PMPRB's guidelines, especially in light of the need for Canada to progressively develop and implement a holistic biomanufacturing strategy that would support Canadians now and in the future.

As a result, Takeda Canada believes that PMPRB moving forward independently to self-monitor and self-evaluate is concerning. Any monitoring and evaluation regime should be led by a party independent of the PMPRB, and this should be done only after the government pauses on these pharmaceutical drug reforms in advance of July 1, 2021 to collaboratively work with industry on the common objectives of affordability and patient access.

Takeda Canada Inc.

**Legal Disclaimer:**

This submission and any other engagement in consultations with the PMPRB regarding the Patented Medicines Regulations, as amended, and related Guidelines are without prejudice and are not intended and should not be interpreted as supporting the amendments to the PMPRB Regulations or the Guidelines. Takeda continues to have concerns about the legality of the Patented Medicines Regulations, as amended, and the Guidelines which are the subject of ongoing legal challenges. Takeda reserves its full legal rights to oppose any aspect of the Patented Medicines Regulations and related Guidelines.