



August 31, 2021

Patented Medicine Prices Review Board (PMPRB)
Box L40 Standard Life Centre
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Ottawa, Ontario, K1P 1C1

Submitted via email: pmprb.consultations.cepmb@pmprb-cepmb.gc.ca

Takeda Canada Consultation Response: On the change to the definition of Gap medicines, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions (July 15, 2021)

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.

As members of both Innovative Medicines Canada and BIOTEC Canada, Takeda Canada supports the submissions made by both associations in opposition to the July 15, 2021 proposals. The proposals run contrary to the federal government's stated intent to delay the implementation date of the amendments to the Patented Medicines Regulations (Regulations) until January 1, 2022 to assist with the ongoing COVID-19 pandemic and will have negative impacts for patentees and many other stakeholders.

Takeda Canada echoes IMC's request that the PMPRB discontinue the arbitrary and harmful proposal to change price tests for existing products and their line extensions and maintain a 12-month transition period from the date that the regulatory changes come into force to reflect the Federal government's intent to allow all parties to focus on addressing the COVID-19 pandemic.

In the recently published Drugs for Rare Diseases consultation summary document, Health Canada notes the following action as a "next step" in developing the strategy: "Ensuring Canada's regulatory approach, drug pricing landscape, and research and innovation capacity are

conducive for rare-disease drugs” (Health Canada, 2021 . Building a National Strategy for Drugs for Rare Diseases- What We Heard From Canadians, pg 17).

In the interests of achieving this goal and better aligning Canada’s pharmaceutical policies, Takeda Canada requests the July 15th PMPRB proposals be withdrawn.

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.