Consultation on PMPRB Interim Approach
Takeda Canada Submission
July 18, 2022

Takeda Canada Inc. ("Takeda") is making this submission in response to the request for feedback regarding the Patented Medicine Prices Review Board's (PMPRB) June 30th proposal on its price review approach during the Interim Period.

About Takeda

Takeda is a global pharmaceutical leader founded in 1781. For over 241 years, we've aimed to make an impact on patients' lives by translating science into life-changing medicines. More than a decade ago, Takeda made the strategic decision to become a specialty biologics company and today we have a deep and sustained commitment to developing Drugs for Rare Diseases. Forty percent of our marketed products are drugs for rare diseases and more than 50% of our pipeline products have an orphan drug designation (as per the U.S. FDA and EU EMA definitions of orphan drugs). Our commitment to bringing better health and brighter futures to people around the world is built on a sustainable portfolio of innovative medicines.

Takeda's Comments re: PMPRB Price Review Approach During the Interim Period

Takeda supports an approach that would limit disruption while the new set of guidelines are being finalized for release later this year. Takeda is a proud member of both Innovative Medicines Canada and BIOTECanada and Takeda supports the submissions delivered by both aforementioned organizations as part of this consultation process.

Takeda would like to express the following concerns with the PMPRB proposal:

1. Inconsistency with "Status Quo" if limiting Consumer Price Index (CPI) list price increases
   As one of the two requirements included in the proposed approach, the Interim Guidelines state that an existing patented medicine would not trigger an investigation provided if "its list price does not increase during the Interim Period". This is not consistent with a "Status Quo" approach since "Changes in the Consumer Price Index" is an explicit factor in the Patent Act that should be reflected in both the interim and future Guidelines. List price increase should not be used as grounds for patented drugs to trigger new investigations during the Interim Period.

Takeda Canada Inc.
Bay Adelaide Centre
22 Adelaide Avenue West, Suite 3800
Toronto, M5H 4E3

2. Unclear benchmarking during Interim Period

   Takeda requests that the PMPRB clarify how it will set the compliance benchmark during the Interim Period. In particular, how will the non-excessive average price (NEAP) be applied to existing drugs. Further clarity is also needed for the benchmark to be applied for drugs that had first patented sales during the extended period of uncertainty since the first announcement of PMPRB reforms.

3. Ambiguity on duration of the transition period

   While the amended regulations are effective July 1, 2022, Takeda assumes that the PMPRB will allow at least two reporting periods starting from when the new guidelines are finalized for manufacturers to adjust pricing, where necessary, given the new regime. This would be consistent with the PMPRB's previous commitment to a twelve-month transition period (April 2021).

Takeda also recommends PMPRB to consider the followings when finalizing the interim approach and drafting the new guidelines:

1. Incorporate Patent Act Factors in both the interim approach and future guidelines to reflect relevant case law and PMPRB's legislative mandate to monitor for excessive pricing resulting from patent abuse.

2. Establish a joint PMPRB and industry working group that leverages the expertise of PMPRB and patentees. Their objective can be to work through the operation and technical details of the guidelines, with the intent to formulate a new guidelines package that ensures smooth transition and is consistent with regulatory tools.

3. Ensure pricing policy is consistent and supportive of the broader life science and innovation activities in the Canadian healthcare ecosystem, including the national strategy for drugs for rare diseases. Given the number and variety of existing initiatives, projects and proposals focused on improving the treatment of patients with rare diseases, it is critical that the PMPRB ensure that its reform efforts align with the broader governmental strategies, for example, the federal Biomanufacturing and Life Science Strategy. Also for this reason, Takeda believes it is important for the federal government and the provinces to align on a rare disease strategy for Canada before any new pricing guidelines to Drugs for Rare Diseases is finalized, in order to maximize strategic alignment and minimize inadvertent contradiction.

Final thoughts

Takeda would welcome the opportunity to have further dialogue with the PMPRB. Takeda also remains willing to share our knowledge and experience of global best practices to design innovative and inclusive solutions, especially for Drugs for Rare Diseases which represent the most fragile aspect of the Canadian pharmaceutical market. Takeda is fully committed to collaborate with government to ensure Canada an attractive jurisdiction to invest and launch innovative medicines and clinical trials.

Legal Disclaimer:

Takeda understands that the PMPRB intends to apply Guidelines within the framework of amendments to the Patented Medicines Regulations (Regulations), which came into force on July 1, 2022. While Takeda is committed to constructive engagement with the PMPRB, Takeda's engagement should not be interpreted as supporting the validity of the amended Regulations, which remain, as of the date of this submission, under review by the Federal Court of Appeal in Court File No. A-215-20. Takeda reserves the right to oppose any aspect of the amended Regulations, Guidelines, or other decision that exceeds the jurisdiction of the Board.