Consultation on Proposed Amendments to the PMPRB Interim Guidance
Takeda Canada Inc. Submission
August 18, 2023

Takeda Canada Inc. ("Takeda") is making this submission in response to the June 20, 2023, Notice and Comment issued by the Patented Medicines Prices Review Board (PMPRB) on Proposed Amendments to its Interim Guidance policy on price review dated August 18, 2022.

About Takeda

Takeda is a global pharmaceutical leader founded in 1781. For over 240 years, we have been improving patients' lives by translating science into life-changing medicines. 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 is a member of Innovation Medicines Canada (IMC), and we support and endorse IMC's submission to this request for Notice and Comment.

Takeda's Comments re: Proposed Amendments to the Interim Guidance

Takeda commends the Board for re-engaging stakeholders in consultation on a new set of final guidelines, and for extending the interim period to allow more time for the consultation. We urge the Board to anchor this renewed consultation in the values of transparency and public accountability that underpin the PMPRB's Consultation Policy.[1] We agree that the success of the consultation requires a commitment to partnership based on integrity and mutual respect, as outlined in that same policy. To that end, we encourage the Board to establish of a joint PMPRB and industry working group to leverage the expertise of both PMPRB and patentees to develop and work through operational and technical details of the final guidelines and ensure a smooth transition to the new regime. Takeda is willing to contribute to this working group; our knowledge and experience of both Drugs for Rare Diseases and

[1] Patented Medicine Prices Review Board Consultation Policy http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1028&lang=en

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plasma derived therapies would be particularly valuable in that regard.

Takeda appreciates the Board's attempt to supply patentees with early guidance and greater predictability for new medicines currently under review. However, we strongly advocate for expanding the consideration of having been "reviewed" to all relevant medicines with a price within the range of the PMPRB 11 prices. A price test below the median international price is not appropriate and does not reflect PMPRB's mandate to ensure medicine prices are not excessive and to identify patent abuse. The Interim Guidance should be amended to remove any doubt about allowable annual price increases based on the Consumer Price Index (CPI). Currently, the interim guidance only speaks to price increases during the first half of 2022. The interim period has since been extended, and changes in the CPI is a mandatory factor that the Board must consider when assessing if a drug has been sold at an excessive price.

We appreciate the opportunity to share our feedback. We sincerely hope the renewed consultation and extended timeline of the Interim Guidelines will result in a thorough and thoughtful consultation, and final Guidelines that provide appropriate regulatory tools, while supporting a healthy Canadian life science eco-system that is positioned to continue providing Canadians with innovative medicines and healthcare solutions.

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 reserves its full legal rights to oppose any aspect of the Patented Medicines Regulations and related Guidelines.