Better Health, Brighter Future

Scoping Paper for the Consultations on the Board's Guidelines:

Takeda Canada Submission December 20, 2023

Takeda Canada Inc. (Takeda) is pleased to provide comments on the Scoping Paper for the PMPRB Guidelines Consultation and is encouraged by the Board's stated intention that these comments will contribute to a more informed, focused, and productive consultation. We were pleased to hear the new chairperson, Thomas Digby, refer to new beginnings during the December 5th Roundtable, and the overall positive tone of the renewed consultation, to date. We look forward to continuing open engagement with the Board throughout the consultation process.

Takeda is a patient-focused, values-based, global pharmaceutical company committed to creating innovative therapies through research and development. Established in 1781, Takeda positively affects patients' lives by translating science into life-changing medicines, focusing on our core therapeutic areas of neuroscience, gastroenterology, oncology, vaccines, and plasma-derived therapies. As a leader in rare diseases and plasma-derived therapies, Takeda brings a unique perspective to this renewed consultation on the PMPRB Guidelines.

Takeda has actively participated in development of the submissions of both Innovative Medicines Canada (IMC) and BIOTECanada. Since these two Industry Association submissions reflect our position on the Scoping Paper questions, we will not be providing detailed responses to each question. We will, however, reference which scoping paper themes relate to each of our comments via footnotes.

Takeda asserts that the Guidelines should continue to rely on voluntary compliance by manufacturers[1] and should be based on the principles of predictability, consistency,

[1] Theme 4: Investigation and Referral to Hearing, Question 4.3.

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sustainability, functionality, and fairness[2]. In addition, the Guidelines should provide enough detail to allow manufacturers to determine with reasonable certainty a product's pricing strategy throughout its lifecycle[3].

The PMPRB Board must develop the new Guidelines in the context of the mandate of the PMPRB, namely, to address patent abuse by charging excessive prices for patented medicines. Affordability, healthcare sustainability, cost-effectiveness assessment and broader Health Technology Assessment are the purview of other players in the pharmaceutical ecosystem, and not part of the PMPRB's statutory mandate.[4]

Drugs For Rare Diseases

Recent federal government commitments to ongoing investment in a National Strategy for Drugs for Rare Diseases (DRDs) is a welcome step towards addressing the unique challenges of drugs for rare diseases. It positions Canada favourably among peer countries after years of being the only developed country without a rare disease strategy.

New PMPRB Guidelines must align with federal government and provincial life science and rare disease strategies for Canada and consider the impact of the Guidelines on Drugs for Rare Diseases (DRD).[4] A thoughtful and coordinated approach to DRDs will reduce the risk of creating any unintended consequences that may impede rather than support efforts to: improve access to these medicines, make Canada an attractive jurisdiction for the launch of DRDs, and, promote global investment.

[2] Theme 1: Efficient monitoring of Prices without Price Setting, Question 1.1

[3] Theme 4: Investigations and Referral to Hearing, Questions 4.2. Note: although the theme and question are framed around investigations, it is important that the Guidelines provide sufficient detail and predictability so that manufacturers can reasonably predict the price tests that may trigger an investigation.

[4] Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives, Question 5.2. Note: Takeda's position is that the best way for PMPRB to optimize its presence with the broader ecosystem is to strictly adhere to its statutory mandate of mandate of address patent abuse via excessive prices.

Appropriate Scrutiny on Tendered Plasma-Derived Therapies (PDTs)

One aspect of the proposed 2022 PMPRB Guidelines that should be preserved is the acknowledgement of the need for differential treatment for tendered products, notably vaccines. The reasoning behind this distinction is that most tendered products are subject to a competitive tendering process, thereby rendering moot the issue of charging excessive prices.[5]

PDTs are typically subjected to a robust tendering process by the Canadian Blood Services and Héma Québec. This procurement system for PDTs achieves cost savings by consolidating volumes and soliciting competitive bids from suppliers, with the contract awarded to the bidder or bidders who best meet those criteria. As such, PDTs typically have a similar low risk of excessive pricing as vaccines, and it would be appropriate to provide differential treatment for all tendered products, including PDTs.

Once again, Takeda thanks the Board for the opportunity to provide these comments, and for the renewed approach to the consultation on the Guidelines. Once the Board has reviewed the submissions on the Scoping Paper, Takeda would welcome the opportunity to engage with the PMPRB through working groups and other meetings to assist with developing an appropriate approach to pricing and access, particularly for DRDs, and to share examples of unnecessary PMPRB review and investigation of PDTs. To that end, we seek an opportunity to meet with the PMPRB in a virtual or in-person meeting at its earliest convenience, to discuss how new Guidelines can be drafted and operationalized in a way that is consistent with the PMPRB's statutory mandate, while striking a balance with the interests of stakeholders and Canadian patients.

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

[5] Theme 1: Efficient monitoring of Prices without Price Setting, Theme 4: Investigations and Referral to Hearing. Note: There are no specific questions that relate to treatment of PDTs, however, reserving investigations into PDT prices will likely improve PMPRB excessive price monitoring efficiency by not focusing the Board's efforts on situations with a low risk of excessive pricing, thus avoiding unnecessary investigations.